

Sent: 8/12/2020 8:30:47 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: CLOSE HOLD: Update on Various Rollout Timing

Hi Renate,

Thanks for the updates – slide 6 C3PO and JHU have bbe

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 4:15 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Parker, Ashley (NIH/OD) [E] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]
Wood, Gretchen (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Seigfreid, Kim (NIH/OD) [E] [b6]
Schwetz, Tara (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]
Subject: CLOSE HOLD: Update on Various Rollout Timing

Hi all:

I wanted to update you on the timing of our various rollouts.

AstraZeneca Phase 3 Vaccine:

The AstraZeneca announcement for Friday is off. We discussed with NIAID and below are the current plans, although we expect to speak with AZ communication folks today or tomorrow. I will update you if this changes.

- 1) If AZ trial starts next week, NIH/NIAID will just issue a press release since Francis is out and Tony may be out the latter part of next week. We would then schedule a telebriefing for the following week as an update on vaccine trials.
- 2) If AZ trial starts the week of August 24, we will hold a media telebriefing with video in connection with the launch (which also is an opportunity to provide a general update on vaccine trials).

ACTIV-4:

I checked the below times with NHLBI and they said it works for Gary Gibbons. There is an ICD call scheduled that day, which is why we would start at 10:00 a.m. rather than 9:30 a.m. **Let me know if this time works and we'll lock it in.**

Thursday, August 27

10:00-10:30 a.m.: Pre-call
10:30-11:30 a.m.: Telebriefing
12:00-12:30 p.m.: Social Media Event

NCATS Convalescent Plasma Clinical Trials:

Next couple of weeks:

OWS providing \$55 million in funding for NCATS Administrative Supplements to NYU/Einstein and Vanderbilt to supplement existing trials to limit COVID-19 complications in hospitalized patients. Not currently part of ACTIV; not sure if that will change. NCATS thinks the administrative supplements will be awarded in the next couple of weeks. See attached slides.

We recommended that NCATS do a news release to explain the purpose of the trials and the additional funding, but we are not recommending a telebriefing.

ACTIV-1:

Early to mid-September:

NCATS said companies do not appear to have a strong interest in participating in our rollout, so it would likely just be NIH/FNIH.

I'll keep you posted as things solidify.

Thanks,
Renate

From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 7/31/2020 2:46:17 PM
To: [b6] Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto, Gregory [b6]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Stratton, Benjamin [bstratton@DELOITTE.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]
Subject: ACTIV Preclinical - Data Portal Implementation
Location: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])
Start: 5/21/2020 1:00:00 PM
End: 5/21/2020 2:00:00 PM
Show Time As: Tentative
Recurrence: (none)



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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 7/31/2020 2:45:46 PM
To: Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Gatto, Gregory [b6]; Diamond, Michael [b6]; Mason, Stephen [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Baric, Toni C [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]

Subject: ACTIV Preclinical - Network of BSL 3 / 4 sites

Location: <https://deloitte.zoom.us/j/9171111111> [b6]

Start: 6/9/2020 3:00:00 PM

End: 6/9/2020 4:00:00 PM

Show Time As: Tentative

Recurrence: (none)



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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 2/26/2021 7:21:43 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Automatic reply: ACTIV Pre-call

Good afternoon, I will be out of the office this afternoon and will have no access to emails. If you need assistance, please contact Deanna Garner at b6 I'll reply as soon as I am back online.

From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 2/25/2021 2:57:44 PM
To: [b6], Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6] Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6] Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; [b6]
CC: Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]
Subject: ACTIV Preclinical - Long Hauler Discussion
Location: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])
Start: 3/26/2021 3:00:00 PM
End: 3/26/2021 4:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Hi all,

Rescheduling this series due to a conflict with another recurring meeting for many of our attendees.

Best,
Harrison



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From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 2/25/2021 2:57:45 PM
To: Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6]; [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; [b6]
CC: Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]
Subject: ACTIV Preclinical - Long Hauler Discussion
Location: <https://deloitte.zoom.us> [b6]
Start: 2/26/2021 4:00:00 PM
End: 2/26/2021 5:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Updating title to reflect new focus on long-term sequelae of COVID-19

Hi all,

Rescheduling this series due to a conflict with another recurring meeting for many of our attendees.

Best,
Harrison

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Sent: 7/22/2020 12:16:50 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]
Subject: RE: ACTIV Daily Update July 22
Attachments: Summary of NIH Convalescent Plasma Trials 062420_233PM.xlsx

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Wednesday, July 22, 2020 8:04 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Subject: RE: ACTIV Daily Update July 22

Vaccine distribution

https://www.statnews.com/2020/07/22/confusion-spreads-over-system-to-determine-priority-access-to-covid-19-vaccines/?utm_source=STAT+Newsletters&utm_campaign=21ebd8b91a-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-21ebd8b91a-149573977

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Wednesday, July 22, 2020 7:17 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: ACTIV Daily Update July 22

Slides for today's war room call, Wednesday July 22.

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, July 16, 2020 10:31 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];

Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]
Subject: ACTIV Daily Update 20200716.pptx

Slides for today's war room call, Thursday July 16. Joe Menetski will be joining us.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/14/2020 4:22:48 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 8/7/2020 12:00:00 PM

End: 8/7/2020 12:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Friday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E];

Attendees: Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique

Attendees: (NIH/NCATS) [E]; Carver, Trea (NIH) [C]

Extending through August

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/14/2020 4:20:13 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]

Subject: Daily ACTIV Calls

Location: Dial-in: Passcode:

Start: 8/6/2020 6:30:00 PM

End: 8/6/2020 7:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Thursday from 2:30 PM to 3:00 PM

Required Attendees: Wholley, David; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Carver, Trea (NIH) [C]; Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]

Extending through August

Dial-in:

Passcode:

Dr. Tabak as Leader:

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/14/2020 4:17:51 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 8/5/2020 12:00:00 PM

End: 8/5/2020 12:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David (FNIH) [T], Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E];

Optional Attendees: Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Attendees: Simon, Dina (NIH/OD) [C], Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E], Carver, Trea (NIH) [C];

Attendees: Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]

Extending through August

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

Sent: 7/10/2020 12:35:22 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd], Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: FW: Clinical/Preclinical therapy information request form

Would it be useful to include additional language in the auto reply that says "We have received your submission and will contact you once a decision is

From: Pan Zheng [b6]
Sent: Friday, July 10, 2020 8:19 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]
Subject: Re: Clinical/Preclinical therapy information request form

Dear David,

Any decision on including [b4] in second round consideration? I remembered the team will make decision this week.

Thanks,

Pan

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, June 30, 2020 8:07 PM
To: Pan Zheng [b6]; Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]
Subject: RE: Clinical/Preclinical therapy information request form

Thanks, Pan. Actually our prioritization team, which consists of top ID scientists from industry, the public sector, and academia does look at all the data. They are currently prioritizing agents for potential future inclusion into specific master protocols that ACTIV would implement. However, so there is no avoidance of doubt, I do want to make sure you know we are not funding individual trials run by other sponsors. So if Oncoimmune is looking for money from us to run their own trial, you are likely wasting your time. And I know your time is very valuable. If you want to withdraw consideration of your agent from ACTIV, please let me know. Otherwise we will include it with the other agents we are prioritizing—many of whose sponsors, I must say, have data that they too insist is very compelling.

Regards,
David

From: Pan Zheng; [REDACTED] b6
Sent: Tuesday, June 30, 2020 1:18 PM
To: Wholley, David (FNIH) [T] [REDACTED] b6; Adam, Stacey (FNIH) [T] [REDACTED] b6; Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Cc: Menetski, Joseph (FNIH) [T] [REDACTED] b6
Subject: Re: Clinical/Preclinical therapy information request form

Dear David and Stacey,

I understand that you may receive thousand of requests. You may not have time to read all. I actually cc'ed Stacey with the ACTIV survey PDF file when I sent emails to Dr. Kiley at NHLBI a week ago.

I just want to emphasize the most important data here. The goal of ACTIV or any NIH, FNIH coordinated activities is to find the cure quickly. The goal is not to test early stage products to fish out the effective treatment.

As of June 9, this Phase III study reached the 70th subject. As of June 26, all 70 patients passed 14 days or more in follow up.

The mortality is the most important safety test. Here we report that there are 3 patients passed away within 14 days after randomization. This gave the 14 day mortality as 4.3%. When we compare this number with all the known mortality rates for severe and critical COVID-19, this appears to be a very strong indicator that our clinical trial may indeed save lives.

b4

Hope this could help the decision making.

Best,

Pan

Pan Zheng, MD, PhD

Chief Medical Officer

OncoImmune, Inc.

PO Box 83430
Gaithersburg, MD 20883-3430

T: [b6]

[b6]

From: Wholley, David (FNIH) [T] [b6]

Sent: Monday, June 29, 2020 9:19 PM

To: Pan Zheng [b6]; Liu, Paul (NIH/NHGRI) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]

Cc: Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Clinical/Preclinical therapy information request form

Thanks Pan. Then you are in the process already.

From: Pan Zheng [b6]

Sent: Monday, June 29, 2020 7:59 PM

To: Liu, Paul (NIH/NHGRI) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]

Subject: Fw: Clinical/Preclinical therapy information request form

Dear David,

We submitted the survey on June 9.

Thanks,
Pan

From: activ_submission@fnih.org <activ_submission@fnih.org>

Sent: Tuesday, June 9, 2020 10:32 AM

To: Pan Zheng [b6]

Subject: Clinical/Preclinical therapy information request form

Pan,

Thank you for completing the ACTIV COVID-19 Clinical & Preclinical Candidate Compound Portal survey. This email serves as a confirmation that we have received your completed survey.

Thank You

APAR0000016729

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/14/2020 4:15:53 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel]
Subject: Daily ACTIV Calls
Location: Dial-in: Passcode:

Start: 8/5/2020 12:00:00 PM
End: 8/5/2020 12:30:00 PM
Show Time As: Tentative

Required Attendees: Wholley, David, Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]
Optional Attendees: Simon, Dina (NIH/OD) [C]; Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Carver, Trea (NIH) [C]; Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]

Extending through August

Dial-in:
Passcode:

Dr. Tabak as Leader:

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/14/2020 4:13:08 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 8/4/2020 12:00:00 PM

End: 8/4/2020 12:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Tuesday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Simon, Dina (NIH/OD) [C]; Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Carver, Trea (NIH) [C];

Attendees: Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]

Scheduling through August

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 6/30/2020 2:24:00 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Available for A Quick Call

Hi Ashley, yes I can talk.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, June 30, 2020 10:12 AM
To: Menetski, Joseph (FNIH) [T] [b6]
Subject: Available for A Quick Call

Hi Joe,

It seems you are available until 10:30am – do you have minute for a quick call?

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



National Institutes of Health

Sent: 7/20/2020 2:58:59 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Time Sensitive: Dr. Collins' Hever Meeting July 24

Sorry, our emails got crossed. Companies listed on slide 6 know their status as indicated in the

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, July 20, 2020 10:56 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: Time Sensitive: Dr. Collins' Hever Meeting July 24

Hi Ashley,

I thinking about this further. Would FC be okay with just using slide 6 and not using slide 5? That way none of the internal review pieces are an issue?

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Monday, July 20, 2020 10:39 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: Time Sensitive: Dr. Collins' Hever Meeting July 24

Hi Ashley,

I have updated the slides for 5-6 to the most current versions of those slides in the attached. I think these slides should be okay to share if we think they will not be distributed too broadly.

I do have some apprehensions for the neutralizing Ab slide, as many of the companies being evaluated are at HEVER and some are not yet aware of their status. Do you think this is a particular sensitivity to avoid?

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 20, 2020 9:49 AM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: George, Jill (NIH/OD) [E]
Subject: Time Sensitive: Dr. Collins' Hever Meeting July 24

Hi Stacey,

Francis is scheduled to give an ACTIV update to the Hever group this Friday 7/24. Attached are slides he would like to present but he asked that I check with you to confirm if it's OK to share slides 5 and 6 with this group and if there is confidential information that should not be shown to Hever.

Pre-reads are due today – please let me know if slides 5-6 are OK to share or if you have edits. For your reference, I've included the slides we shared with this group for the June update.

Hi Jill – for ease of doing things quickly, I am cc'ing you in case you have any minor visual edits.

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



National Institutes of Health

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/21/2020 7:19:30 PM
To: Hardesty, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tajalli, Ada (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]
Subject: ACTIV Leadership Team Call #7
Location: <https://fnih.zoom.us/j/9121212121> b6
Start: 8/26/2020 7:00:00 PM
End: 8/26/2020 8:30:00 PM
Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]
Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos, FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege, Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/21/2020 7:13:57 PM
To: Hardesty, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Tajalli, Ada (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]
Subject: ACTIV EC & Working Group Co-Chair Meeting
Location: <https://fnih.zoom.us> b6
Start: 8/14/2020 7:30:00 PM
End: 8/14/2020 9:00:00 PM
Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John
Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

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Sent: 7/1/2020 1:25:06 PM
To: Elsaid, Olivia [oelsaid@deloitte.com]
Subject: RE: FW: Correction to ACTIV Leadership Meeting Slide 2

Thanks!!

From: Elsaid, Olivia <oelsaid@deloitte.com>
Sent: Wednesday, July 1, 2020 9:15 AM
To: Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: FW: Correction to ACTIV Leadership Meeting Slide 2

Hi Ashley,

Please find attached the updated full set of slides. I've also attached an extract of the Attendee and Agenda slide to share with Dr. Collins. Please let us know if you see any additional modifications that should be made and thank you for your help!

Best,
Olivia

Olivia Elsaid
Deloitte Consulting LLP
Tel/Direct: [b6] Mobile: [b6]
www.deloitte.com

From: Gonzalez, Nina <ningonzalez@deloitte.com>
Sent: Wednesday, July 1, 2020 8:41 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>
Cc: Melencio, Cheryl (FNIH) [T] [b6]
Subject: Re: FW: Correction to ACTIV Leadership Meeting Slide 2

Hi Ashley,

Certainly, and yes we saw that edit. Olivia was doing some last minute edits so I will ask her to send to you ASAP.

Thanks,

Nina

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, July 1, 2020 8:35:43 AM
To: Gonzalez, Nina <ningonzalez@deloitte.com>; Wholley, David (FNIH) [T] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>
Cc: Melencio, Cheryl (FNIH) [T] [b6]
Subject: [EXT] RE: FW: Correction to ACTIV Leadership Meeting Slide 2

Hi Nina,

Can I please have a copy of the revised version? We usually share the logo slide and agenda for Dr. Collins' meetings with the Secretary.

Hopefully you saw the note to switch William Lee for Thomas Cihlar for Gilead.

Thanks so much,
Ashley

From: Gonzalez, Nina <ningonzalez@deloitte.com>

Sent: Wednesday, July 1, 2020 7:01 AM

To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6] oelsaid <oelsaid@deloitte.com>

Cc: Melencio, Cheryl (FNIH) [T] [b6]

Subject: RE: FW: Correction to ACTIV Leadership Meeting Slide 2

Hi David,

Yes we will bake that into our process and provide the meeting slide to Ashley the day prior to review. Also, we'll keep a master version to go back to if needed.

Thanks,

Nina

From: Wholley, David (FNIH) [T] [b6]

Sent: Tuesday, June 30, 2020 10:58:42 PM

To: Parker, Ashley (NIH/OD) [E] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>

Cc: Melencio, Cheryl (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>

Subject: [EXT] RE: FW: Correction to ACTIV Leadership Meeting Slide 2

We seem to be having serial problems with version control and appropriate assignment of partners to the right categories on the attendee slide. Can I ask that we submit the attendee slide to Ashley Parker a day before each Executive Committee and Leadership Team meeting in future so we have this right, and that we keep a library slide with the correct information that can be sourced for all presentations? Thank you. David

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Tuesday, June 30, 2020 10:56 PM

To: oelsaid <oelsaid@deloitte.com>; Wholley, David (FNIH) [T] [b6]

Cc: Melencio, Cheryl (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>

Subject: RE: FW: Correction to ACTIV Leadership Meeting Slide 2

Fred Hutch and RTI are not industry – these should be non-profit, right?

From: Elsaid, Olivia <oelsaid@deloitte.com>

Sent: Tuesday, June 30, 2020 8:02 PM

To: Wholley, David (FNIH) [T] [b6]

Cc: Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>

Subject: RE: FW: Correction to ACTIV Leadership Meeting Slide 2

Hi All,

That looks like it was an old version of the slide. Cheryl confirmed with us so we moved Steve Paul to FNIH and added Amgen, gsk, and Evotec. Let us know if anything else looks missing to you and we can update - the latest version is in the attached.

Best,
Olivia

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Sent: 7/21/2020 6:06:42 PM
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CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]

Subject: ACTIV Leadership Team Pre-call

Location: see webex below

Start: 8/24/2020 4:00:00 PM

End: 8/24/2020 4:30:00 PM

Show Time As: Tentative

Required Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

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Subject: ACTIV Leadership Call #6
Location: <https://fnih.zoom.us/j/91211111111> b6
Start: 7/29/2020 6:30:00 PM
End: 7/29/2020 8:00:00 PM
Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeiding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lee, William; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]

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Sent: 6/30/2020 1:17:40 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-lepone|m]
Subject: Re: Moderna and Novavax

To complicate things a bit or at least come to a decision — Dr. Collins has a Senate appropriations hearing on Thursday and we have the number of industry partners for ACTIV written in his oral testimony. We currently state there are 18 industry partners — do we want to include Moderna and Novavax and day there are 20?

We will leave as 18 until a decision is made.

Thank you,
Ashley

On Jun 29, 2020, at 6:17 PM, Parker, Ashley (NIH/OD) [E] [REDACTED] b6 wrote:

Great points. The latter would be the easiest solution but defer to David's preference on adding to the leadership team — I don't think this was preferred previously. Any non-profits not on the leadership team would also need to be removed.

If we move forward with listing "all partners", yes we would need to update the sites and include academics as well.

Thank you,
Ashley

On Jun 29, 2020, at 5:32 PM, Santos, Michael (FNIH) [T] [REDACTED] b6 wrote:

That approach is fine with me, though if we go that route do you plan to add the affiliations of other Working Group members under the "Non-profit" heading? E.g., in

the Vaccines WG, we have some other organizations (e.g., Stanford, U of Washington, UCSF, Duke, Baylor, Penn) represented that do not have Leadership Team members.

Alternatively, if we want to either leave things as-is or invite additional companies to the Leadership Team, I think those would also be reasonable solutions.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, June 29, 2020 5:22 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Gorman, Greta (FNIH) [T] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: RE: Moderna and Novavax

I don't see an issue doing that but am asking my team in case there are any red flags I do not see.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, June 29, 2020 5:20 PM
To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Moderna and Novavax

Hi David and Cheryl,

I understand that Moderna and Novavax have members on the vaccines working group but are not members of the leadership team. Given we list all companies who represent the working groups on the NIH ACTIV <https://www.nih.gov/research-training/medical-research-initiatives/activ#organizations> and FNIH website <https://fnih.org/what-we-do/programs/activ-partnership>, I wanted to confirm that we should add their company names?

If this is OK – I will also suggest to our team and FNIH we change the current headings as “leadership organizations” to something like “ACTIV Partners”? Others who are not leadership i.e. BMGF are listed under this umbrella and I understand we want to be clear to note the difference.

Thank you,
Ashley

b6

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Meeting ID: **b6**

Passcode: **b6**

Find your local number: <https://fnih.zoom.us> **b6**

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/2/2020 1:40:47 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Chen, Helen [qingchen@deloitte.com]; oelsaid [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]

Subject: Pre-Call: ACTIV EC & WG Chairs Meeting

Location: see webex below

Start: 7/14/2020 5:45:00 PM

End: 7/14/2020 6:15:00 PM

Show Time As: Tentative

Required Attendees: Adam, Stacey (FNIH) [T], Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia, Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T], Stratton, Ben, Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T], Collins, Francis (NIH/OD) [E], Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]

Optional Attendees: McManus, Ayanna (NIH/OD) [E], Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

Join Webex meeting

Meeting number (access code)

b6

Meeting password

b6

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You can also dial and enter your meeting number.

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Call-in toll number (US/Canada)

Global call-in numbers

Join using Microsoft Lync or Microsoft Skype for Business

Dial @lync.webex.com

Join the meeting

If you are a host, [click here to view host information.](#)

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/23/2020 3:42:18 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 6/26/2020 8:30:00 PM

End: 6/26/2020 9:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Friday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E];

Freire, Maria (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina

(NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]

Due to unavoidable conflict, rescheduling Friday's call to 4:30 p.m.

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 2/19/2021 7:06:53 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]

Subject: Canceled: ACTIV Call "War Room"
Location: Dial-in: [b6] Passcode: [b6]

Start: 2/26/2021 1:00:00 PM
End: 2/26/2021 1:30:00 PM
Show Time As: Free

Recurrence: Weekly
every Friday from 8:00 AM to 8:30 AM
Required Attendees: Wholley, David (FNIH) [T], Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rutter, Joni (NIH/NCATS) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]

Due to conflict, this meeting is cancelled for Friday, February 26.

Dial-in: [b6]
Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/24/2020 3:31:12 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 6/25/2020 2:00:00 PM

End: 6/25/2020 2:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Thursday from 2:30 PM to 3:00 PM

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Freire, Maria (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]

Due to change in Dr. Collins schedule, this call has been rescheduled to 10-10:30 a.m.

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/17/2020 7:58:21 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Chen, Helen [qingchen@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]

Subject: ACTIV Leadership Team #6 Pre-call

Location: see webex below

Start: 7/27/2020 8:00:00 PM

End: 7/27/2020 8:30:00 PM

Show Time As: Tentative

Required Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

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Sent: 6/24/2020 12:51:26 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: FW: ACTIV Daily Update 20200624.pptx

Good morning Michelle,

Is

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Wednesday, June 24, 2020 8:46 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Jonson, Samantha (NIH/NCATS) [E] [b6]
Subject: RE: ACTIV Daily Update 20200624.pptx

Copying Sam re the call.

And see my note to Michelle this morning about the databases – there should be no confusion.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, June 24, 2020 8:44 AM
To: Austin, Christopher (NIH/NCATS) [E] [b6]
Subject: RE: ACTIV Daily Update 20200624.pptx

Is this the 10am call or a different time? I would like to join if possible – too many databases and I'm not certain that I've seen this one.

Thanks!
Ashley

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Wednesday, June 24, 2020 8:35 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200624.pptx

Just got confirmation that the "Kevin" on the call today with NCATS staff to discuss ACTIV access to the CT tracker is indeed Kevin Bugin. I'll let you know outcome.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, June 24, 2020 7:23 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]
Subject: ACTIV Daily Update 20200624.pptx

For this morning's war room, Wednesday June 24.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/17/2020 7:55:15 PM
To: Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tajalli, Ada (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]
Subject: ACTIV Leadership Call #6
Location: <https://fnih.zoom.us/j/9121212121> b6
Start: 7/29/2020 6:30:00 PM
End: 7/29/2020 8:00:00 PM
Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeiding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lee, William; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]
Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan, Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Hardesty, Rebecca (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Sent: 6/23/2020 4:14:53 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Potential ACTIV Partnership

I'm discussing developing general responses for FAQ's with Ellen this afternoon -- I think this would be useful.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, June 23, 2020 8:02 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Potential ACTIV Partnership

No, let's discuss this am

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, June 22, 2020 9:55 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: FW: Potential ACTIV Partnership
Importance: High

Hi David,

Please see below -- Beigene is interested in becoming a partner with ACTIV. While we can certainly address their interest to submit 2 candidates for review -- should we direct them your way regarding joining ACTIV?

Thanks,
Ashley

From: COVID19 Reporting [b6]
Sent: Monday, June 22, 2020 8:20 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Potential ACTIV Partnership
Importance: High

And, we're on a roll. I'm not sure how you handle these types of inquiries. Guidance would be appreciated!

From: Bryce Davies [b6]
Date: Sunday, June 21, 2020 at 1:07 AM
To: COVID19 Reporting [b6] "Gorman, Greta (FNIH) [T]" [b6]
Subject: Potential ACTIV Partnership

Dear NIH and FNIH team,

My name is Bryce Davies, I am a Senior Director with BeiGene, a biopharmaceutical company that has developed products in the oncology and heme-oncology space. We currently have two potential COVID-19 treatment candidates that we are wanting to bring to the global fight against the pandemic. I understand that there is a portal for submission of ideas and therapeutic candidates, but we would like to explore the possibility of becoming an industry partner with the ACTIV program. BeiGene has extensive experience in the development of new treatments and the operational, regulatory and scientific considerations involved. I strongly believe that, in addition to our potential treatments, we could provide valuable support and insight to this critically important initiative.

I am more than happy to set up a call with our clinical development team to review our two candidates and provide further information on BeiGene.

Regards

Bryce Davies

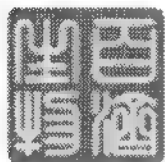
Senior Director, Clinical Operations

BeiGene Aus Pty. Ltd.

Mobile [REDACTED] b6

Email [REDACTED] b6

Website: www.beigene.com



BeiGene

From: Young, John; [b6]
Sent: 8/23/2020 6:24:18 AM
To: Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]
CC: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; [b6]
Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Gatto, Gregory [b6]
Hawk, Harrison [hhawk@deloitte.com]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; [b6]
Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; [b6] CIV
USARMY MEDCOM USAMRIID (USA) [b6]; Rodriguez, Robin D [b6]
[b6]; ros Alvarez@deloitte.com
Subject: Re: ACTIV Preclinical - In vivo Strategy

Dear Clint

Thanks for sharing. The results with the Baric E6 cells are very promising.

Best regards

John

On Sun, 23 Aug 2020 at 2:29 AM, Florence, Clint (NIH/NIAID) [E] [b6] wrote:

All –

APAR0000004760

b5

b5

Thanks –

Clint

From: rosalvarez@deloitte.com

When: 10:00 AM - 11:00 AM August 21, 2020

Subject: ACTIV Preclinical - In vivo Strategy

Location: <https://deloitte.zoom.us>

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 8/17/2020 3:57:27 AM
To: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hawk, Harrison [hhawk@deloitte.com]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6];
Subject: RE: ACTIV Preclinical - In vivo Strategy
Attachments: 20200814_PRECLINICAL_In Vivo Strategy_v2.docx

Hi all,

Please see attached for the meeting notes from last week. Please let me know if you suggest any modifications.

Regards,

Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: [b6]
www.deloitte.com

-----Original Appointment-----

From: Alvarez, Rosa Maria
Sent: Wednesday, June 3, 2020 5:53 PM
To: Alvarez, Rosa Maria; [b6]; Menetski, Joseph (FNIH) [T]; Young, John; Colvis, Christine (NIH/NCATS) [E]; [b6] Nancy Haigwood; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Rodriguez, Robin D; [b6] Parker, Ashley (NIH/OD) [E]; Hawk, Harrison; Ottinger, Elizabeth (NIH/NCATS) [E]; Gatto, Gregory
Subject: ACTIV Preclinical - In vivo Strategy
When: Friday, August 14, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 8/17/2020 1:20:03 AM
To: Diamond, Michael [b6]; Young, John [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Gatto, Gregory [b6]; Mason, Stephen [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Baric, Toni C [b6]; Kara Carter [b6]; [b6] Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Kolykhalov, Alexander A. [b6]; Michael Sofia [b6]; Denison, Mark (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39e8760f26024042916d630592b4c15f-mark.deniso]; Mark Krystal [b6]; Johnson, R. Paul [b6]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hawk, Harrison [hhawk@deloitte.com]; Tomas Cihlar [Tomas.Cihlar@gilead.com]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwood.oh]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Sumit Chanda [b6]; Challberg, Mark (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=28a89f5b6a384b1a864e1ef36d058da7-mchallberg]; Sciotti, Rick (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afc7c6959cb44a0aa7de771f2ebb4871-sciottirj]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Chen, Helen Q. [qingchen@deloitte.com]; Prabhavathi Fernandes [b6]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; De wit, Emmie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634c7f8074f64222aad020f2950269c1-dewite]; [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]

Subject: ACTIV Preclinical Network - Prioritization of Preclinical-stage agents

Location: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

Start: 8/18/2020 3:00:00 PM

End: 8/18/2020 4:00:00 PM

Show Time As: Tentative

Recurrence: (none)

-----Re-sending this invite as some of you have mentioned that you don't have it on your calendar-----

Hi all,

The objective of this meeting is to discuss the scoring for the 26 assigned preclinical agents. Also invited to this meeting is the team that put together the BSL 3 /4 network to support the discussion around next steps for these preclinical agents.

Look forward to the discussion on Tuesday 11am. If this time does not work for you, please let me know alternative time slots for 8/18 and 8/19. I will try my best to accommodate everyone's schedule.



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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 8/21/2020 1:33:35 PM
To: Young, John [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [hhawk@deloitte.com]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]
Subject: RE: ACTIV Preclinical - In vivo Strategy

Hi all,

Please see below for the agenda for today's meeting. Let me know if you suggest any modifications.

Agenda Topic	Duration	Facilitator
Continue discussion on NHP field guide to make available to the public	20 mins	Nancy Haigwood, Jay Rappaport
Discuss small animal model field guide status and plan for next meeting	15 mins	Cat Lutz Isis Kanevsky
Update on BEI viral stock production (if any new updates since Wednesday)	10 mins	Clint Florence
Align on next steps and owners	15 mins	Joe Menetski, Rosa Alvarez

Best,
Rosa

-----Original Appointment-----

From: Alvarez, Rosa Maria
Sent: Wednesday, June 3, 2020 5:53 PM
To: Young, John; Parker, Ashley (NIH/OD) [E]; Alvarez, Rosa Maria; [b6] Menetski, Joseph (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; [b6] Nancy Haigwood; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] [b6] Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Rodriguez, Robin D;

b6; Hawk, Harrison; Ottinger, Elizabeth (NIH/NCATS [E]; Gatto, Gregory
Cc: Hewitt, Judith (NIH/NIAID) [E]
Subject: ACTIV Preclinical - In vivo Strategy
When: Friday, August 21, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://deloitte.zoom.us> **b6**

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 8/10/2020 5:17:46 PM
To: Diamond, Michael [b6]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Gatto, Gregory [b6]; Mason, Stephen [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Baric, Toni C [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hawk, Harrison [hhawk@deloitte.com]
Subject: RE: ACTIV Preclinical - Network of BSL 3 / 4 sites
Attachments: 20200804_PRECLINICAL Working Group_BSL 3-4 Network_d1.docx

Hi all,

Please see attached for the summary notes from our last meeting. Please let us know if you have any questions.

Regards,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: [b6]
www.deloitte.com

-----Original Appointment-----

From: Alvarez, Rosa Maria
Sent: Thursday, June 4, 2020 2:29 PM
To: Alvarez, Rosa Maria; Diamond, Michael; Young, John; [b6]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Gatto, Gregory; Mason, Stephen; Baric, Ralph; Baric, Toni C; Parker, Ashley (NIH/OD) [E]; Hawk, Harrison
Subject: ACTIV Preclinical - Network of BSL 3 / 4 sites
When: Tuesday, August 4, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

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From: Connelly, Sarah [sconnelly@deloitte.com]
Sent: 3/1/2021 9:02:25 PM
To: Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Young, John [b6] [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6] Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; [b6] FNIH [fnih@roseliassociates.com]
CC: Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]
Subject: RE: ACTIV Preclinical - Long Hauler Discussion
Attachments: 20210226_ACTIV Preclinical - Long Hauler Discussion_Notes_vF.pdf

Hi All,

Thank you all for attending our ACTIV preclinical long hauler discussion on Friday. Please see below for the actions that came out of the meeting and attached for the notes from our discussion, and let us know if you all have any additions or amendments.

Action Items:

- Group members will ask around in their circles to determine what additional research is being conducted to develop PASC animal models
- Subgroup members from industry will determine what if, anything, is happening at their companies
- The group will consider organizing the appropriate policy folks to discuss moving animals out of BSL3

Warm Regards,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: +1 571 882 8905
www.deloitte.com

APAR0000004771

-----Original Appointment-----

From: Hawk, Harrison <hhawk@deloitte.com>

Sent: Friday, October 16, 2020 1:07 PM

To: Hawk, Harrison; Young, John; [REDACTED] b6 Menetski, Joseph (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; [REDACTED] b6 Nancy Haigwood; [REDACTED] b6 CIV USARMY MEDCOM USAMRIID (USA); [REDACTED] b6 Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Rodriguez, Robin D; [REDACTED] b6 Parker, Ashley (NIH/OD) [E]; Ottinger, Elizabeth (NIH/NCATS) [E]; Gatto, Gregory; Jonson, Samantha (NIH/NCATS) [E]; Connelly, Sarah; Fessel, Josh (NIH/NHLBI) [E]; [REDACTED] b6 FNIH

Cc: [REDACTED] b6

Subject: ACTIV Preclinical - Long Hauler Discussion

When: Friday, February 26, 2021 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

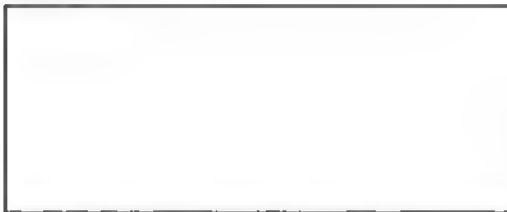
Where: <https://deloitte.zoom.us> [REDACTED] b6

Updating title to reflect new focus on long-term sequelae of COVID-19

Hi all,

Rescheduling this series due to a conflict with another recurring meeting for many of our attendees.

Best,
Harrison



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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 8/5/2020 7:55:25 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: ACTIV preclinical manuscripts described this morning
Attachments: ACTIV in vitro CELL-HOST-MICROBE-S-20-01287 (1).pdf; Hewitt et al ACTIV Animal Models complete.pdf

Dear All,

Here are the 2 ACTIV manuscripts that have been submitted to Cell Host and Microbe.

They have turned out very interesting and the content should help the field come to some consensus on the models and the development process. I am sure the team would appreciate any feedback you would like to provide.

Best regards,

joe

From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 8/11/2020 8:55:08 PM
To: [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto, Gregory [b6]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D [b6] Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Se032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6]
Subject: RE: ACTIV Preclinical - Data Portal Implementation

Hi all,

Please see below for the agenda for Thursday's meeting. Please let me know if you suggest any modifications. Look forward to our discussion.

Agenda Topic	Duration	Facilitator
Revisiting the study-level animal model data approach <ul style="list-style-type: none"> Take a step back and discuss overall goals and objectives - what type of data and analysis would be useful to have and how would it be used? Discuss proposed capabilities to implement such data platform Discuss ACTIV members' bandwidth to take this on 	35 mins	Samantha Jonson Liz Ottinger Subgroup Discussion
Align on action items and next steps	10 mins	Joe Menetski Rosa Alvarez

Best regards,
Rosa

Rosa M. Alvarez
 Deloitte Consulting LLP
 Mobile: [b6]
 www.deloitte.com

-----Original Appointment-----

From: Alvarez, Rosa Maria
Sent: Thursday, April 23, 2020 10:33 AM

APAR0000004776

To: Alvarez, Rosa Maria [b6] Hewitt, Judith (NIH/NIAID) [E]; [b6] Gatto, Gregory; Young, John; Colvis, Christine (NIH/NCATS) [E]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS) [E]; [b6]; Rodriguez, Robin D; [b6]; Jonson, Samantha (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]
Cc: Florence, Clint (NIH/NIAID) [E]; Mason, Stephen
Subject: ACTIV Preclinical - Data Portal Implementation
When: Thursday, August 13, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://deloitte.zoom.us> [b6]

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 8/11/2020 8:43:25 PM
To: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hawk, Harrison [hhawk@deloitte.com]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]
Subject: RE: ACTIV Preclinical - In vivo Strategy
Attachments: 20200807_PRECLINICAL Working Group_in vivo strategy_v1.docx

Hi all,

Please see attached for the summary notes from our meeting last Friday 8/7. Please let us know if you suggest any modifications.

Best,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: [b6]
www.deloitte.com

-----Original Appointment-----

From: Alvarez, Rosa Maria
Sent: Wednesday, June 3, 2020 5:53 PM
To: Alvarez, Rosa Maria; [b6] Menetski, Joseph (FNIH) [T]; Young, John; Colvis, Christine (NIH/NCATS) [E]; [b6] Nancy Haigwood; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Rodriguez, Robin D; [b6] Parker, Ashley (NIH/OD) [E]; Hawk, Harrison; Ottinger, Elizabeth (NIH/NCATS) [E]; Gatto, Gregory
Subject: ACTIV Preclinical - In vivo Strategy
When: Friday, August 7, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://deloitte.zoom.us> [b6]

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 8/11/2020 8:24:30 PM
To: [b6] Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto, Gregory [b6]; Young, John [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6]; Hawk, Harrison [hhawk@deloitte.com]
Subject: RE: ACTIV Preclinical - Data Portal Implementation
Attachments: 20200806_PRECLINICAL Working Group_Data Portal Implementation_v1.docx

Hi all,

Please see attached for our meeting notes from last week 8/6. Please let us know if you suggest any modifications.

Regards,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: [b6]
www.deloitte.com

-----Original Appointment-----

From: Alvarez, Rosa Maria
Sent: Thursday, April 23, 2020 10:33 AM
To: Alvarez, Rosa Maria; [b6] Hewitt, Judith (NIH/NIAID) [E]; [b6] Gatto, Gregory; Young, John; Colvis, Christine (NIH/NCATS) [E]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS) [E]; Stratton, Benjamin; [b6] Rodriguez, Robin D; [b6] Jonson, Samantha (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]
Cc: Florence, Clint (NIH/NIAID) [E]; Mason, Stephen; Hawk, Harrison
Subject: ACTIV Preclinical - Data Portal Implementation
When: Thursday, August 6, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

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From: Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC]
Sent: 8/11/2020 5:19:58 PM
To: Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hawk, Harrison [hhawk@deloitte.com]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Kara Carter [b6]
Subject: RE: ACTIV Preclinical - In vivo Strategy
Attachments: MVB WVB Criteria.pptx

All –

Please see the attached slide deck which outlines lot release and characterization metrics which lots produced by BEI will be compared to in order to judge acceptability for animal challenges. BEI and NIAID have agreed to these.

Thanks –

Clint

-----Original Appointment-----

From: Alvarez, Rosa Maria <rosalvarez@deloitte.com>

Sent: Sunday, June 14, 2020 10:11 PM

To: Alvarez, Rosa Maria; Colvis, Christine (NIH/NCATS) [E]; Menetski, Joseph (FNIH) [T]; Young, John;

[b6]; Nancy Haigwood; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Charette, Marc (NIH/NHLBI) [E]; Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Rodriguez, Robin D; Anderson, James (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Hawk, Harrison; Ottinger, Elizabeth (NIH/NCATS) [E]; Gatto, Gregory

Subject: ACTIV Preclinical - In vivo Strategy

When: Friday, August 14, 2020 10:00 AM-11:00 AM (UTC-05 00) Eastern Time (US & Canada).

Where: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

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From: Young, John [b6]
Sent: 8/11/2020 1:31:19 PM
To: Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]
CC: rosavarez@deloitte.com; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hawk, Harrison [hhawk@deloitte.com]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]
Subject: Re: ACTIV Preclinical - In vivo Strategy

Dear Clint

Thanks for the update. Sounds like good and rapid progress. Fingers crossed that the stocks are good.

Best regards

John

On Tue, Aug 11, 2020 at 2:29 PM Florence, Clint (NIH/NIAID) [E] [b6] > wrote:

All –

b5

b5

b5

b5

b5

Thanks

Clint

From: rosalvarez@deloitte.com

When: 10:00 AM - 11:00 AM August 14, 2020

Subject: ACTIV Preclinical - In vivo Strategy

Location: <https://deloitte.zoom.us>

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--
John A.T. Young, PhD
VP and Global Head Infectious Diseases
Roche Pharma Research & Early Development
Roche Innovation Center Basel
F.Hoffmann-La Roche Ltd
Grenzacherstrasse 124
4070 Basel, Switzerland

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PA: Gianni Micheloni

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 8/11/2020 11:51:48 AM
To: Young, John [b6]; Diamond, Michael [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Gatto, Gregory [b6]; Mason, Stephen [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Baric, Toni C [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites
Location: https://deloitte.zoom.us/[b6]
Start: 8/11/2020 3:00:00 PM
End: 8/11/2020 4:00:00 PM
Show Time As: Free

Recurrence: (none)

Hi all,

Canceling this meeting today as we will be focusing on the Preclinical Agent Prioritization. I will send a meeting invite for early next week to discuss the Match-Making process for the compounds to be prioritized.

Best,
Rosa

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 8/4/2020 1:24:20 PM
To: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6] Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hawk, Harrison [hhawk@deloitte.com]

Subject: ACTIV Preclinical - In vivo Strategy

Location: <https://deloitte.zoom.us> [b6]

Start: 6/12/2020 2:00:00 PM

End: 6/12/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: (none)

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 8/4/2020 1:24:21 PM
To: Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6]; [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hawk, Harrison [hhawk@deloitte.com]

Subject: ACTIV Preclinical - In vivo Strategy

Location: <https://deloitte.zoom.us/j/9181111111> [b6]

Start: 8/7/2020 2:00:00 PM

End: 8/7/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: (none)

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 7/28/2020 2:24:46 PM
To: Diamond, Michael [b6]; Young, John [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Gatto, Gregory [b6]; Mason, Stephen [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Baric, Toni C [b6]
Subject: RE: ACTIV Preclinical - Network of BSL 3 / 4 sites

Hi all,

Please see below for today's agenda. Please let me know if you suggest any modification.

Agenda Topic	Duration	Facilitator
Discuss next steps for Preclinical-Stage Agent Prioritization	15 mins	Joe Menetski
Review scoring used for Clinical Agent Prioritization and discuss scoring for Preclinical-Stage Agent Prioritization	30 mins	John Young, Joe Menetski
Align on action items and next steps	5 mins	Joe Menetski Rosa Alvarez

Regards,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: [b6]
www.deloitte.com

-----Original Appointment-----

From: Alvarez, Rosa Maria
Sent: Thursday, June 4, 2020 2:29 PM
To: Diamond, Michael; Young, John; Parker, Ashley (NIH/OD) [E]; Alvarez, Rosa Maria [b6]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Gatto, Gregory; Mason, Stephen; Baric, Ralph; Baric, Toni C
Subject: ACTIV Preclinical - Network of BSL 3 / 4 sites

When: Tuesday, July 28, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://deloitte.zoom.us> **b6**

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 7/29/2020 2:08:28 PM
To: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ACTIV Preclinical - In vivo Strategy
Attachments: 20200724_PRECLINICAL Working Group_in vivo strategy_v1.docx

Hi all,

Please see attached for our meeting notes from Friday. Also below are the action items summary. Let me know if you suggest any modifications.
Apologies for the delay!

Action Items:

- Cat to finalize list of mouse experts (sending individual emails to her list of experts)
- Cat to draft context for the email invitation
- Joe to send the invite to the small animal sub-committee

Best,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: [b6]
www.deloitte.com

-----Original Appointment-----

From: Alvarez, Rosa Maria
Sent: Wednesday, June 3, 2020 5:53 PM
To: Alvarez, Rosa Maria; [b6]; Menetski, Joseph (FNIH) [T]; Young, John; Colvis, Christine (NIH/NCATS) [E]; [b6]; Nancy Haigwood; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Rodriguez, Robin D; [b6] Parker, Ashley (NIH/OD) [E]
Subject: ACTIV Preclinical - In vivo Strategy

When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://deloitte.zoom.us/j/9181234567>

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 7/23/2020 2:28:37 AM
To: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6] Cat.Lutz@jax.org; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ACTIV Preclinical - In vivo Strategy
Attachments: 20200717_PRECLINICAL Working Group_in vivo strategy_v1.docx

Hi all,

Apologies for the delay. Please find attached the notes from our meeting last week (7/17). Please let us know if you have any questions.

Regards,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: [b6]
www.deloitte.com

-----Original Appointment-----

From: Alvarez, Rosa Maria
Sent: Wednesday, June 3, 2020 5:53 PM
To: Alvarez, Rosa Maria; ccolvis@mail.nih.gov; Menetski, Joseph (FNIH) [T]; Young, John; Colvis, Christine (NIH/NCATS) [E]; [b6] Nancy Haigwood; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Rodriguez, Robin D; [b6] Parker, Ashley (NIH/OD) [E]
Subject: ACTIV Preclinical - In vivo Strategy
When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 7/23/2020 2:23:36 AM
To: Young, John [b6]; [b6] Hewitt, Judith (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto,
Gregory [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Stratton, Benjamin
[bstratton@DELOITTE.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D
[b6] Jonson, Samantha (NIH/NCATS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Florence, Clint (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]
Subject: RE: ACTIV Preclinical - Data Portal Implementation
Attachments: 20200716_PRECLINICAL Working Group_Data Portal Implementation_v1.docx

Hi all,

Apologies for the delay. Attached are the meeting notes from last week's meeting. Please let us know if you suggest any changes.

Also, our agenda for tomorrow's meeting is the following:

Agenda Topic	Duration	Facilitator
Review draft of small animal product pages	25 mins	Samantha Jonson Liz Ottinger
Review final version of NHP product pages	10 mins	Samantha Jonson Liz Ottinger
Discuss potential data maintenance process	20 mins	Samantha Jonson Liz Ottinger
Align on action items and next steps	5 mins	Joe Menetski Rosa Alvarez

Looking forward to our discussion tomorrow.

Best,
Rosa

-----Original Appointment-----

From: Alvarez, Rosa Maria
Sent: Thursday, April 23, 2020 10:33 AM
To: Young, John; Alvarez, Rosa Maria; [b6] Hewitt, Judith (NIH/NIAID) [E]; [b6] Gatto,

Gregory; Colvis, Christine (NIH/NCATS) [E]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS) [E]; Stratton, Benjamin; [b6] Rodriguez, Robin D; [b6]; Jonson, Samantha (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]
Cc: Florence, Clint (NIH/NIAID) [E]
Subject: ACTIV Preclinical - Data Portal Implementation
When: Thursday, July 23, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://deloitte.zoom.us/j/9181234567> [b6]

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From: Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC]
Sent: 7/3/2020 12:39:11 AM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gatto, Greg [b6]; Grobler, Jay [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Subject: Re: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Michel Nussenzeig Michel Nussenzweig [b6]

Thomas J. Hope [b6]

On 7/2/20, 5:45 PM, "Menetski, Joseph (FNIH) [T]" [b6] wrote:

Dear Preclinical Working group,

ACTIV is working with OWS to setup a mAb summit. We were asked to solicit suggestions and recommendations from our working groups for those that would be appropriate to contribute to this event. Please see the note below and let me know if there is anyone that would fill the roles described.

Thank you,
Joe

Subject: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

All,

I hope you're doing well. As you may know, OWS, NIH, and FNIH are hosting a mAb scientific summit mid to end of August. The objective of the summit is to facilitate discussion on mAb science and address how to optimize development and therapeutic use of mAbs going forward.

The summit will be facilitated in a panel format, with each panel focused on a white paper written and circulated in advance on a key topic in the space. We have attached a few slides capturing the key topics and the white paper format.

We are writing to you today to get your recommendations on experts that may be able to address each of the key topics, with a focus on 3 roles:

1. White paper author: Expert to write a paper providing an overview of the various positions on specific key topics in advance of the summit
2. Panelist: Additional experts to provide alternative perspectives on a panel during the summit to include industry partners
3. Moderator: Facilitator to develop questions for the panel and synthesize positions from white paper author and responses from panelists after the summit

We have included a slide in the attached file to be filled in with your recommendations on each of these roles for the key topics. We are looking for diversity in the panel. If you could please provide input by EOD on Monday July 7th, that would be great.

Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
Ph- 3 [b6]
Cell- [b6]
Fax- 301-619-7230
email - [b6]

CLASSIFICATION: UNCLASSIFIED

APAR0000004802

From: Punturieri, Antonello (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CA7F3106E5F24B5CB5E933C6EE7A6BC7-PUNTURIERIA]
Sent: 7/2/2020 9:52:21 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gatto, Greg [b6]; Grobler, Jay [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Subject: RE: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Suggest:

Jonathan Abraham
e-mail: [b6]

Massachusetts Consortium
on Pathogen Readiness,
Boston, MA, USA.

FOR:

Lessons from other fields or Effector function or Antibody-dependent enhancement

Tony

-----Original Message-----

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Thursday, July 2, 2020 5:43 PM

To: Adams, Peter (OS/ASPR/BARDA) [b6]; Alvarez, Rosa <rosalvarez@deloitte.com>;
Anderson, Annaliesa [b6]; Baric, Ralph [b6]; Carter, Kara
[b6]; Charette, Marc (NIH/NHLBI) [E] [b6]; Cihlar, Tomas
[b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Deming, Damon
(FDA/CDER) [b6]; Diamond, Michael [b6]; Duncan, Ken
(NIH/NHLBI) [E] [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh
Ellen (NIH/OD) [E] [b6]; Florence, Clint (NIH/NIAID) [E] [b6]; Gadbois,
Gatto, Greg [b6]; Grobler, Jay
[b6]; Nancy Haigwood [b6]; Hewitt, Judith (NIH/NIAID) [E]
Jonson, Samantha (NIH/NCATS) [E] [b6]; Lutz, Cat
[b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E]
[b6]; Parker, Ashley (NIH/OD) [E] [b6]; Payne, David
[b6]; Punturieri, Antonello (NIH/NHLBI)
[E] [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Rao, Srinivas
[b6]; Rappaport, Jay [b6]; Stegmeier, Frank
[b6]; Young, John [b6]
Cc: MENETSKY, JOSEPH (FNIH) [T] [b6]
Subject: FW: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Dear Preclinical Working group,

ACTIV is working with OWS to setup a mAb summit. We were asked to solicited suggestions and recommendations from our working groups for those that would be appropriate to contribute to this event. Please see the note below and let me know if there is anyone that would fill the roles described.

Thank you,
Joe

Subject: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

All,

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We are writing to you today to get your recommendations on experts that may be able to address each of the key topics, with a focus on 3 roles:

1. White paper author: Expert to write a paper providing an overview of the various positions on specific key topics in advance of the summit
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We have included a slide in the attached file to be filled in with your recommendations on each of these roles for the key topics. We are looking for diversity in the panel. If you could please provide input by EOD on Monday July 7th, that would be great.

Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
Ph- [b6]
Cell [b6]
Fax- 301-619-7230
email - [b6]

CLASSIFICATION: UNCLASSIFIED

APAR0000004804

From: Tomas Cihlar [b6]
Sent: 7/6/2020 6:43:19 AM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbanc.ema]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gatto, Greg [b6]; Grobler, Jay [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Subject: RE: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Dear Joe,
In addition to names already suggested, colleagues from NIH VRC should be considered namely John Mascola and Rick Koup; as well as perhaps more representatives from biotech - Kara suggested several, I would add Larry Zeitlin (MappBio CSO) and Ester Falconer (AbCellera Head of R&D).
Best regards, Tomas

-----Original Message-----

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Thursday, July 02, 2020 2:43 PM
To: Adams, Peter (OS/ASPR/BARDA) [b6]; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa [b6]; Baric, Ralph [b6]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E] [b6]; Tomas Cihlar [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Deming, Damon (FDA/CDER) [b6]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [b6]; Florence, Clint (NIH/NIAID) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Gatto, Greg [b6]; Grobler, Jay [b6]; Nancy Haigwood [b6]; Hewitt, Judith (NIH/NIAID) [E] [b6]

[b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]; Lutz, Cat
[b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E]
[b6]; Parker, Ashley (NIH/OD) [E] [b6]; Payne, David
[b6]; Punturieri, Antonello (NIH/NHLBI)
[E] [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Rao, Srinivas
[b6]; Rappaport, Jay [b6]; Stegmeier, Frank
[b6]; Young, John [b6]
Cc: Menetski, Joseph (FNIH) [T]
Subject: [EXTERNAL] FW: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

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Thank you,
Joe

Subject: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

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Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
Ph- [b6]
Cell- [b6]
Fax- 301-619-7230
email - [b6]

CLASSIFICATION: UNCLASSIFIED

From: Prabha Fernandes [b6]
Sent: 7/5/2020 8:33:55 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Alvarez, Rosa' [rosalvarez@deloitte.com]; 'Anderson, Annaliesa' [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; 'Carter, Kara' [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; 'Cihlar, Tomas' [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; 'Diamond, Michael' [b6]; 'Duncan, Ken' [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fessel.jp]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; 'Gatto, Greg' [b6]; 'Grobler, Jay' [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; 'Lutz, Cat' [b6]; 'Nestle, Frank' [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; 'Payne, David' [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Rao, Srinivas' [b6]; 'Rappaport, Jay' [b6]; 'Stegmeier, Frank' [b6]; 'Young, John' [b6]
Subject: RE: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Hi Joe,
You have many names, but here are a couple from Infectious diseases expertise..
S. A. Plotkin, [b6] (Measles vaccine - immune response characterization)
Pamela Bjorkman, Caltech, [b6] (Zika immune response)
Bali Pulendran, Institute for Immunity, Stanford. [b6]
(host factors, that impact immunity).

Regards,
Prabha

-----Original Message-----

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Sent: Thursday, July 02, 2020 5:43 PM
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Nicole Kilgore, MS, PMP
 Deputy Joint Project Manager
 JPM CBRN Medical
 1564 Freedman Dr, Fort Detrick, MD 21702
 Ph- b6
 Cell b6
 Fax- 301-619-7230
 email - b6

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From: Punturieri, Antonello (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CA7F3106E5F24B5CB5E933C6EE7A6BC7-PUNTURIERIA]
Sent: 6/30/2020 11:40:24 AM
To: Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; [b6]; [b6]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; [b6]; [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbcd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Prabhavathi Fernandes [b6]; Diamond, Michael [b6]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; [b6]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [b6]; CIV USARMY MEDCOM USAMRIID (USA) [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting
Attachments: STAT2 signaling as double-edged sword [b5] model June 2020.pdf

All,

In case you have not seen the attached:

[b5]

Tony

APAR0000004807

Antonello Punturieri, M.D., Ph.D.
Program Director, COPD and Environment Division of Lung Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
6705 Rockledge Drive, 403K MSC 7952
Bethesda, MD 20892

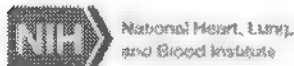
T [b6]

[b6]

COVID-19

Get the latest public health information from CDC: <https://www.coronavirus.gov>

Get the latest research information from NIH: <https://grants.nih.gov/policy/natural-disasters/corona-virus.htm>



50 YEARS

*Celebrating 50 years of progress in pulmonary science with
the Division of Lung Diseases*

From: Nancy Haigwood [b6]
Sent: 7/5/2020 8:18:16 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiyp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Subject: Re: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Joe,
I believe I previously suggested to this group, or a subgroup:
[b6], Vanderbilt any of these roles, highly knowledgeable about antibodies from humans that are directed to all diseases
[b6], structural biologists who now has a new affiliation at La Jolla Institute for Immunology and leads a large antibody-based therapy consortium, would be great for the white paper, also an outstanding speaker
John Mascola at the VRC or Mark Connors at NIAID intramural, both human mAb experts.

Best wishes,
Nancy

On 7/2/20, 2:44 PM, "Menetski, Joseph (FNIH) [T]" [b6] wrote:

Dear Preclinical Working group,

ACTIV is working with OWS to setup a mAb summit. We were asked to solicit suggestions and recommendations from our working groups for those that would be appropriate to contribute to this event. Please see the note below and let me know if there is anyone that would fill the roles described.

Thank you,
Joe

Subject: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

All,

I hope you're doing well. As you may know, OWS, NIH, and FNIH are hosting a mAb scientific summit mid to end of August. The objective of the summit is to facilitate discussion on mAb science and address how to optimize development and therapeutic use of mAbs going forward.

The summit will be facilitated in a panel format, with each panel focused on a white paper written and circulated in advance on a key topic in the space. We have attached a few slides capturing the key topics and the white paper format.

We are writing to you today to get your recommendations on experts that may be able to address each of the key topics, with a focus on 3 roles:

1. White paper author: Expert to write a paper providing an overview of the various positions on specific key topics in advance of the summit
2. Panelist: Additional experts to provide alternative perspectives on a panel during the summit to include industry partners
3. Moderator: Facilitator to develop questions for the panel and synthesize positions from white paper author and responses from panelists after the summit

We have included a slide in the attached file to be filled in with your recommendations on each of these roles for the key topics. We are looking for diversity in the panel. If you could please provide input by EOD on Monday July 7th, that would be great.

Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
Ph- [REDACTED]
Cell [REDACTED]
Fax- 301-619-7230
email - [REDACTED]

CLASSIFICATION: UNCLASSIFIED

From: Young, John [b6]
Sent: 7/5/2020 6:45:11 PM
To: Kara Carter [b6]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gatto, Greg [b6]; Grobler, Jay [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiena]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]
Subject: Re: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

I would also recommend [b6] (Scripps), [b6] (Duke), [b6] (Fred Hutch, Seattle),

On Sun, Jul 5, 2020 at 6:05 PM Kara Carter [b6] wrote:
Hi Joe,

I suggest the following folks, but don't have a sense for the role they should play with regard to white paper author, panelist or moderator.

[b6] - previously Head of Discovery Research North America for Sanofi Pasteur, currently at BMGF. Expertise in ADE and broadly neutralizing influenza antibodies.

[b6] Regeneron. Head of their Ebola antibody program. Focus on clinical efficacy and antibody combinations.

[b6] - Vanderbilt. Identification of neutralizing antibodies from convalescent patient serum to emerging

viral pathogens.

[b6] - Scripps. Identification and characterization of neutralizing antibodies.

Jonathan Abraham - Harvard. Antibodies to emerging viruses. Focus on deciphering roles of effector function for both neutralizing and non-neutralizing antibodies.

[b6] - You know him well, but assessment of potential and combination of neutralizing antibodies to emerging viral pathogens.

[b6] - Just Biotherapeutics - an Evotec company. Antibody optimization and manufacturability. This is a critical aspect that I think is missing for the key roles captured in slide 3.

[b6] - Global Head of Biologics for Sanofi. Antibody optimization and manufacturability. Same comment as above.

Best,
Kara

Kara Carter, PhD
Executive Vice President Infectious Disease

[b6] (Mobile)

[b6]
www.evotec.com

-----Original Message-----

From: Menetski, Joseph (FNIH) [T] [b6]

Sent: Thursday, July 2, 2020 5:43 PM

To: Adams, Peter (OS/ASPR/BARDA); [b6]; Alvarez, Rosa [b6]salvarez@deloitte.com>;

Anderson, Annaliesa [b6]; Baric, Ralph [b6]; Kara Carter

[b6]; Charette, Marc (NIH/NHLBI) [E] [b6]; Cihlar, Tomas

[b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Deming,

Damon (FDA/CDER) [b6]; Diamond, Michael [b6]

Duncan, Ken [b6]; Fernandes, Prabhavathi [b6];

Fessel, Josh (NIH/NHLBI) [E] [b6]; Florence, Clint (NIH/NIAID) [E]

[b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Gatto, Greg

[b6]; Grobler, Jay [b6]; Nancy Haigwood [b6]

Hewitt, Judith (NIH/NIAID) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E]

[b6]; Lutz, Cat [b6]; Nestle, Frank [b6]

Ottinger, Elizabeth (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E]

[b6]; Payne, David [b6]

[b6]; Punturieri, Antonello (NIH/NHLBI) [E] [b6]; Qashu,

Felicia (NIH/OD) [E] [b6]; Rao, Srinivas [b6]; Rappaport, Jay

[b6]; Stegmeier, Frank [b6]; Young, John

[b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]

Subject: FW: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

[EXTERNAL]

Dear Preclinical Working group,

ACTIV is working with OWS to setup a mAb summit. We were asked to solicit suggestions and

recommendations from our working groups for those that would be appropriate to contribute to this event. Please see the note below and let me know if there is anyone that would fill the roles described.

Thank you,
Joe

Subject: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

All,

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Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702

Ph- [b6]
Cell [b6]

Fax- 301-619-7230

email - [b6]

CLASSIFICATION: UNCLASSIFIED

STATEMENT OF CONFIDENTIALITY.

This email and any attachments may contain confidential, proprietary, privileged and/or private information. If received in error, please notify us immediately by reply email and then delete this email and any attachments from your system. Thank you!

<https://www.evotec.com/en/about/site-information/data-protection-us>

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John A.T. Young, PhD
VP and Global Head Infectious Diseases
Roche Pharma Research & Early Development
Roche Innovation Center Basel
F.Hoffmann-La Roche Ltd
Grenzacherstrasse 124
4070 Basel, Switzerland
Mobile [REDACTED]
Mail to [REDACTED]

PA Gianni Micheloni

Phone [REDACTED]
Mobile [REDACTED]
Mail to [REDACTED]

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From: Kara Carter [b6]
Sent: 7/5/2020 4:09:25 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fessel.jp]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gatto, Greg [b6]; Grobler, Jay [b6]; Haigwood, Nancy [b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [john.young.jy3@roche.com]
Subject: RE: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Joe,
One more: [b6] - UT Austin. Identification of therapeutic antibodies to viruses.
Kara

Kara Carter, PhD
Executive Vice President Infectious Disease
[b6] (Mobile)
[b6]
www.evotec.com

-----Original Message-----

From: Kara Carter
Sent: Sunday, July 5, 2020 12:06 PM

APAR0000004812

To: 'Menetski, Joseph (FNIH) [T]' [b6]; Adams, Peter (OS/ASPR/BARDA)
[b6]; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa
[b6]; Baric, Ralph [b6]; Charette, Marc (NIH/NHLBI) [E]
[b6]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E]
[b6]; Deming, Damon (FDA/CDER) [b6]; Diamond, Michael
[b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi
[b6]; Fessel, Josh (NIH/NHLBI) [E] [b6]; Florence, Clint
(NIH/NIAID) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Gatto, Greg
[b6]; Grobler, Jay [b6]; Nancy Haigwood [b6]; Hewitt,
Judith (NIH/NIAID) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E]
[b6]; Lutz, Cat [b6]; Nestle, Frank [b6];
Ottinger, Elizabeth (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E]
[b6]; Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [b6]; Qashu,
Felicia (NIH/OD) [E] [b6]; Rao, Srinivas [b6]; Rappaport, Jay
[b6]; Stegmeier, Frank [b6]; Young, John [b6]
Subject: RE: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Hi Joe,

I suggest the following folks, but don't have a sense for the role they should play with regard to white paper author, panelist or moderator.

[b6] - previously Head of Discovery Research North America for Sanofi Pasteur, currently at
BMGF. Expertise in ADE and broadly neutralizing influenza antibodies.
[b6] - Regeneron. Head of their Ebola antibody program. Focus on clinical efficacy and antibody
combinations.
[b6] - Vanderbilt. Identification of neutralizing antibodies from convalescent patient serum to
emerging viral pathogens.
[b6] - Scripps. Identification and characterization of neutralizing antibodies.
[b6] - Harvard. Antibodies to emerging viruses. Focus on deciphering roles of effector
function for both neutralizing and non-neutralizing antibodies.
[b6] - You know him well, but assessment of potential and combination of neutralizing antibodies
to emerging viral pathogens.
[b6] - Just Biotherapeutics - an Evotec company. Antibody optimization and manufacturability.
This is a critical aspect that I think is missing for the key roles captured in slide 3.
[b6] - Global Head of Biologics for sanofi. Antibody optimization and manufacturability. Same
comment as above.

Best,
Kara

Kara Carter, PhD
Executive Vice President Infectious Disease

[b6] (Mobile)
[b6]
www.evotec.com

-----Original Message-----

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Thursday, July 2, 2020 5:43 PM
To: Adams, Peter (OS/ASPR/BARDA) [b6]; Alvarez, Rosa <rosalvarez@deloitte.com>;
Anderson, Annaliesa [b6]; Baric, Ralph [b6]; Kara Carter
[b6]; Charette, Marc (NIH/NHLBI) [E] [b6]; Cihlar, Tomas
[b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Deming, Damon
(FDA/CDER) [b6]; Diamond, Michael [b6]; Duncan, Ken
[b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh
(NIH/NHLBI) [E] [b6]; Florence, Clint (NIH/NIAID) [E] [b6]; Gadbois,
Ellen (NIH/OD) [E] [b6]; Gatto, Greg [b6]; Grobler, Jay
[b6]; Nancy Haigwood [b6]; Hewitt, Judith (NIH/NIAID) [E]
[b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]; Lutz, Cat
[b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E]
[b6]; Parker, Ashley (NIH/OD) [E] [b6]; Payne, David
[b6]; Punturieri, Antonello (NIH/NHLBI)
[E] [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Rao, Srinivas
[b6]; Rappaport, Jay [b6]; Stegmeier, Frank
[b6]; Young, John [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

[EXTERNAL]

Dear Preclinical Working group,

APAR0000004812

ACTIV is working with OWS to setup a mAb summit. We were asked to solicit suggestions and recommendations from our working groups for those that would be appropriate to contribute to this event. Please see the note below and let me know if there is anyone that would fill the roles described.

Thank you,
Joe

Subject: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

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We have included a slide in the attached file to be filled in with your recommendations on each of these roles for the key topics. We are looking for diversity in the panel. If you could please provide input by EOD on Monday July 7th, that would be great.

Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
Ph- [REDACTED]
Cell [REDACTED]
Fax- 301-619-7230
email - [REDACTED]

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APAR0000004812

From: Rappaport, Jay [b6]
Sent: 7/4/2020 8:33:54 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiyp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gatto, Greg [b6]; Grobler, Jay [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Subject: Re: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Dear Joe and All,
I would recommend the following :
1. [b6] (Harvard. MGH)
2. [b6]; Duke
3. [b6] Rockefeller University
4. [b6]; HiFiBio Therapeutics; Cambridge, Mass./Paris, France

Best ,
Jay

Jay Rappaport, Ph.D.
Director and Chief Academic Officer
Tulane National Primate Research Center
Division of Comparative Pathology

Professor, Department of Microbiology and Immunology
Tulane University School of Medicine
Tulane University

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Covington, LA
70433-8915

Tel [b6]
Fax 985-871-6569

On 7/2/20, 4:45 PM, "Menetski, Joseph (FNIH) [T]" [b6] wrote:

External Sender. Be aware of links, attachments and requests.

Dear Preclinical Working group,

ACTIV is working with OWS to setup a mAb summit. We were asked to solicit suggestions and recommendations from our working groups for those that would be appropriate to contribute to this event. Please see the note below and let me know if there is anyone that would fill the roles described.

Thank you,
Joe

Subject: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

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Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702

Ph- [b6]
Cell- [b6]

Fax- 301-619-7230

email - [b6]

CLASSIFICATION: UNCLASSIFIED

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 6/30/2020 7:51:37 PM
To: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: NHP needs follow up

Great, copying Joe.

From: Anderson, James (NIH/OD) [E] [b6]
Sent: Tuesday, June 30, 2020 3:28 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: NHP needs follow up

David,

I am working with the same assumptions you note. We have already provided about 400 Rhesus to NIAID and BARDA since April.

Jim

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, June 30, 2020 3:25 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: NHP needs follow up

Francis and Jim:

I checked with Joe Menetski about our conversation this morning. Please see below. I think the major point is that the '250-400' estimate, in addition to being somewhat off (depending on which kind of primate you are talking about), applies only to the number of animals that the Preclinical WG thought would be needed to service the proposed ACTIV clinical trials, plus those needed for model validation. It does not include the universe of animals needed to do any other COVID-19 testing, including what could be requested from OWS, BARDA, or NIH investigators over time, which could be triaged through the Preclinical WG. The WG did not have a good way to estimate the volume of such requests, and were not certain what kinds of requests were included in the volume Jim gave this morning (7 requests since April). This is food for thought before your discussion with Tony Fauci.

David

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Tuesday, June 30, 2020 12:07 PM
To: Wholley, David (FNIH) [T] [b6]

Cc: Menetski, Joseph (FNIH) [T]

b6

Subject: NHP needs follow up

David,

Thank you for sharing some of the discussion about NHP use and management that you had this morning with NIH leadership. I wanted to clarify a few things about that discussion, including some detail for when this comes up again.

In late April, we provided a very rough estimate for how many NHP would be needed for testing therapeutics that have been prioritized through ACTIV related activities. We separated NHP needs into 2 species (Rhesus and African Greens) and 2 overall categories of work (model validation and therapeutic testing).

The team projected a need for 450 Rhesus per year for model testing of vaccines and neutralizing antibodies (approximately half for each approach).

The team projected the need for 260 African Green Monkeys per year for model testing of therapeutics that are likely to influence late stage COVID-19 disease (inflammation, coagulopathies and lung function).

For each of these species, the team believes that approximately 20-50 animals will be needed for model validation (this is included in the numbers for each species above). These validation studies include age dependence, route of infection and comparisons to active agents that are in the clinic and will provide information on the translatability of the results from NHP to humans.

The estimates above do not include any studies that have been suggested by any of the ICs or any efforts that are external to ACTIV (e.g. OWS or BARDA).

The team recognized that the actual NHP ABSL3 space may be as limiting as the animals themselves, so facility space should be prioritized to match the animal priorities.

Let me know what else could help the discussion.

Best,
Joe

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

b6 fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19. fnih.org/pandemic



From: Young, John [b6]
Sent: 7/3/2020 6:35:41 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
CC: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gatto, Greg [b6]; Grobler, Jay [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]
Subject: Re: FW: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

David Ho (Columbia University) (Panelist)

On Thu, Jul 2, 2020 at 11:45 PM Menetski, Joseph (FNIH) [T] [b6] wrote:
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Subject: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

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Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702

Ph- b6
Cell
Fax- 301-619-7230

email - b6

CLASSIFICATION: UNCLASSIFIED

--
John A.T. Young, PhD
VP and Global Head Infectious Diseases

APAR0000004818

Roche Pharma Research & Early Development
Roche Innovation Center Basel
F. Hoffmann-La Roche Ltd
Grenzacherstrasse 124
4070 Basel, Switzerland

Mobile: [REDACTED]
Mail to: [REDACTED] **b6**

PA: Gianni Micheloni

Phone: [REDACTED]
Mobile: [REDACTED]
Mail to: [REDACTED] **b6**

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From: Anderson, James (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]
Sent: 6/19/2020 2:00:02 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ACTIV Daily Update 20200619.pptx

And they are working on a publication that summarizes all that is known about the models.

Jim

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, June 19, 2020 9:56 AM
To: Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200619.pptx

These are terrific!

From: Anderson, James (NIH/OD) [E] [b6]
Sent: Friday, June 19, 2020 7:49 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200619.pptx

It anyone is interested. David's slide 2 refers to adding examples of results from animal models to the NCATS ACTIV data portal on June 22. Attached are draft examples of the Syrian Hamster and mouse models.

Jim

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, June 18, 2020 9:28 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: ACTIV Daily Update 20200619.pptx

For tomorrow morning's war room, Friday June 19.

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 6/19/2020 11:56:14 AM
To: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ACTIV Daily Update 20200619.pptx

Thanks very much Jim – these will be a great addition to the portal and the community.

From: Anderson, James (NIH/OD) [E] [b6]
Sent: Friday, June 19, 2020 7:49 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200619.pptx

It anyone is interested. David's slide 2 refers to adding examples of results from animal models to the NCATS ACTIV data portal on June 22. Attached are draft examples of the Syrian Hamster and mouse models.

Jim

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, June 18, 2020 9:28 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: ACTIV Daily Update 20200619.pptx

For tomorrow morning's war room, Friday June 19.

From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 2/13/2021 1:03:50 AM
To: Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto, Gregory [b6]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6]
Subject: RE: Data Portal Implementation
Attachments: 20210212_ACTIV Preclinical_Data Portal Implementation_Notes.docx

Good evening everyone,

Please find the notes from yesterday's meeting attached. Let us know if you have any suggested modifications. Have a great weekend!

Best,
Harrison

-----Original Appointment-----

From: Hawk, Harrison
Sent: Thursday, October 15, 2020 5:33 PM
To: Hawk, Harrison; Connelly, Sarah [b6]; Hewitt, Judith (NIH/NIAID) [E]; [b6] Gatto, Gregory; Young, John; Colvis, Christine (NIH/NCATS) [E]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS) [E]; [b6] Rodriguez, Robin D; Jonson, Samantha (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Mason, Stephen
Subject: Data Portal Implementation
When: Thursday, February 11, 2021 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

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From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 2/12/2021 2:07:26 PM
To: [b6] Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connolly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]
CC: Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]
Subject: RE: ACTIV Preclinical - In Vivo Strategy

Hi all,

Please find the agenda for today's In Vivo Strategy meeting below:

Agenda Topic	Duration	Facilitator
Continued discussion on possible panel topics	30 mins	Joe Menetski Christine Colvis
Discuss future direction for the group	10 mins	Joe Menetski

Best,
Harrison

-----Original Appointment-----

From: Hawk, Harrison
Sent: Friday, October 16, 2020 2:06 PM
To: [b6]; Young, John; Hawk, Harrison; [b6] Menetski, Joseph (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; [b6]
Nancy Haigwood; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Hild, Sheri

(NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Rodriguez, Robin D; [b6] Parker, Ashley (NIH/OD) [E]; Ottinger, Elizabeth (NIH/NCATS) [E]; Gatto, Gregory; Jonson, Samantha (NIH/NCATS) [E]; Connelly, Sarah
Cc: Lumsden, Joanne (NIH/NCATS) [C]
Subject: ACTIV Preclinical - In Vivo Strategy
When: Friday, February 12, 2021 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://deloitte.zoom.us> [b6]

Hi all,

Rescheduling this series due to a conflict with another recurring meeting for many of our attendees.

Best,
Harrison

Join Meeting

Password:

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From: Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/15/2020 4:43:19 PM
To: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Gatto, Greg [b6]; Grobler, Jay [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiJP]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Subject: FW: updated spreadsheet
Attachments: ACTIV PRECLINICAL_Animal Model Inventory_20200514.xlsx

Dear Preclinical working group,

Here is the most current version of the model inventory sheet. Please provide thoughts, comments and suggestions.

Joe

From: Hewitt, Judith (NIH/NIAID) [E] [b6]
Sent: Friday, May 15, 2020 10:54 AM
To: Menetski, Joseph (FNIH) [T] [b6]; Alvarez, Rosa Maria <rosalvarez@deloitte.com>
Subject: FW: updated spreadsheet

Hi Joe & Rosa,

I had questions for Cat & Clint and haven't heard back from either of them, but sharing this with you since you wanted to discuss today.

Thanks,
Judy

From: Hewitt, Judith (NIH/NIAID) [E]

Sent: Thursday, May 14, 2020 8:28 PM

To: Florence, Clint (NIH/NIAID) [E]

b6

Cat Lutz

b6

Subject: updated spreadsheet

Hi Clint & Cat,

Here are the comments we got from the Vaccine group, specifically on the NHP tab, with my comment in red. I added 1-3 to both small animal and NHP tabs, questions for both of you below.

Joe would like to discuss this version in the WG meeting tomorrow. It seems like nobody is telling us to capture less information.

b5

Thanks!
Judy

From: Fessel, Josh (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=294E2BB481D94B83A1917F15338DFE19-FESSELJP]
Sent: 5/13/2020 8:10:11 PM
To: Kara Carter [b6]; Prabha Fernandes [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Anderson, Annaliesa' [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; 'Cihlar, Tomas' [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; 'Diamond, Michael' [b6]; 'Duncan, Ken' [b6]; 'Gatto, Greg' [b6]; 'Grobler, Jay' [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; 'Lutz, Cat' [b6]; 'Nestle, Frank' [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; 'Payne, David' [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Rao, Srinivas' [b6]; 'Rappaport, Jay' [b6]; 'Stegmeier, Frank' [b6]; 'Young, John' [b6]
CC: 'Alvarez, Rosa Maria' [rosalvarez@deloitte.com]
Subject: RE: Slides and document from our meeting
Attachments: Therapeutic information request form-v3 TP PF KC JF docx

Thanks so much, everyone! Adding a very few comments/suggestions to everyone's excellent efforts.

All my best,

Josh

Josh Fessel, MD, PhD

Pronouns: he him his

Medical Officer/Program Director – Vascular Biology & Pulmonary Hypertension

Division of Lung Diseases | National Heart, Lung, and Blood Institute

National Institutes of Health

6705 Rockledge Drive Room 405-F, MSC 7952 | Bethesda, MD 20892-7952

Phone: [b6]

Mobile: [b6] (urgent/emergent use only, please)

Email: [b6]

From: Kara Carter [b6]

Sent: Wednesday, May 13, 2020 1:28 PM

To: Prabha Fernandes [b6]; Punturieri, Antonello (NIH/NHLBI) [E]

[b6]; Menetski, Joseph (FNIH) [T] [b6]; Adams, Peter (OS/ASPR/BARDA)

[b6]; 'Anderson, Annaliesa' [b6]; Baric, Ralph

Charette, Marc (NIH/NHLBI) [E] [b6]; 'Cihlar, Tomas'

[b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Deming, Damon (FDA/CDER)

[b6]; 'Diamond, Michael' [b6]; 'Duncan, Ken'

[b6]; Fessel, Josh (NIH/NHLBI) [E] [b6]; Gatto, Greg'

[b6]; 'Grobler, Jay' <[b6] Hewitt, Judith (NIH/NIAID) [E] [b6]

Jonson, Samantha (NIH/NCATS) [E] [b6]; 'Lutz, Cat' [b6]; 'Nestle, Frank'

[b6]; Ottinger, Elizabeth (NIH/NCATS) [E] <[b6]; Parker, Ashley (NIH/OD)

[E] [b6]; 'Payne, David' [b6]

Qashu, Felicia (NIH/OD) [E] [b6]; 'Rao, Srinivas' [b6]; 'Rappaport, Jay'

[b6]; 'Stegmeier, Frank' [b6]; 'Young, John' [b6]

Cc: 'Alvarez, Rosa Maria' <rosalvarez@deloitte.com>

Subject: RE: Slides and document from our meeting

Sorry. With attachment.



Kara Carter, PhD

Executive Vice President Infectious Disease

[b6] (Mobile)

[b6]
www.evotec.com

From: Kara Carter

Sent: Wednesday, May 13, 2020 12:25 PM

To: 'Prabha Fernandes' [b6]; 'Punturieri, Antonello (NIH/NHLBI) [E]

[b6]; 'Menetski, Joseph (FNIH) [T]' [b6]; 'Adams, Peter (OS/ASPR/BARDA)'

[b6]; 'Anderson, Annaliesa' [b6]; 'Baric, Ralph'

[b6]; 'Charette, Marc (NIH/NHLBI) [E]' [b6]; 'Cihlar, Tomas'

[b6]; 'Colvis, Christine (NIH/NCATS) [E]' [b6]; 'Deming, Damon

(FDA/CDER)' <[b6]; 'Diamond, Michael' [b6]; 'Duncan, Ken'

[b6]; 'Fessel, Josh (NIH/NHLBI) [E]' [b6]; 'Gatto, Greg'

[b6]; 'Grobler, Jay' [b6]; 'Hewitt, Judith (NIH/NIAID) [E]' [b6]

'Jonson, Samantha (NIH/NCATS) [E]' <[b6]; 'Lutz, Cat' [b6]; 'Nestle, Frank'

[b6]; 'Ottinger, Elizabeth (NIH/NCATS) [E]' [b6]; 'Parker, Ashley

(NIH/OD) [E]' <[b6]; 'Payne, David' [b6]

[b6]; 'Qashu, Felicia (NIH/OD) [E]' [b6]; 'Rao, Srinivas'

[b6]; 'Rappaport, Jay' [b6]; 'Stegmeier, Frank' [b6]

'Young, John' [b6]

Cc: 'Alvarez, Rosa Maria' <rosalvarez@deloitte.com>

Subject: RE: Slides and document from our meeting

Hi Joe,

My comments in addition to Prabha's and Tony's.

APAR0000004869

Kara



Kara Carter, PhD

Executive Vice President Infectious Disease

[b6] (Mobile)

[b6]

www.evotec.com

From: Prabha Fernandes <[b6]>

Sent: Wednesday, May 13, 2020 11:11 AM

To: 'Punturieri, Antonello (NIH/NHLBI) [E]' <[b6]>; 'Menetski, Joseph (FNIH) [T]'

<[b6]>; 'Adams, Peter (OS/ASPR/BARDA)' <[b6]>; 'Anderson, Annaliesa'

<[b6]>; 'Baric, Ralph' <[b6]>; Kara Carter <[b6]>

'Charette, Marc (NIH/NHLBI) [E]' <[b6]>; 'Cihlar, Tomas' <[b6]>; 'Colvis,

Christine (NIH/NCATS) [E]' <[b6]>; 'Deming, Damon (FDA/CDER)' <[b6]>

'Diamond, Michael' <[b6]>; 'Duncan, Ken' <[b6]>; 'Fessel, Josh

(NIH/NHLBI) [E]' <[b6]>; 'Gatto, Greg' <[b6]>; 'Grobler, Jay' <[b6]>

'Hewitt, Judith (NIH/NIAID) [E]' <[b6]>; 'Jonson, Samantha (NIH/NCATS) [E]'

<[b6]>; 'Lutz, Cat' <[b6]>; 'Nestle, Frank' <[b6]>; 'Ottinger,

Elizabeth (NIH/NCATS) [E]' <[b6]>; 'Parker, Ashley (NIH/OD) [E]' <[b6]>; 'Payne,

David' <[b6]>; 'Qashu, Felicia (NIH/OD) [E]'

<[b6]>; 'Rao, Srinivas' <[b6]>; 'Rappaport, Jay' <[b6]>

'Stegmeier, Frank' <[b6]>; 'Young, John' <[b6]>

Cc: 'Alvarez, Rosa Maria' <rosalvarez@deloitte.com>

Subject: RE: Slides and document from our meeting

[EXTERNAL]

Hello Joe,

I added my comments on Tony's document.

Sorry I will not be able to webinar-in today.

Have a good meeting!

Regards,

Prabha

From: Punturieri, Antonello (NIH/NHLBI) [E] <[b6]>

Sent: Wednesday, May 13, 2020 9:44 AM

To: Menetski, Joseph (FNIH) [T] <[b6]>; Adams, Peter (OS/ASPR/BARDA) <[b6]>

Anderson, Annaliesa <[b6]>; Baric, Ralph <[b6]>; Carter, Kara

<[b6]>; Charette, Marc (NIH/NHLBI) [E] <[b6]>; Cihlar, Tomas

<[b6]>; Colvis, Christine (NIH/NCATS) [E] <[b6]>; Deming, Damon (FDA/CDER)

<[b6]>; Diamond, Michael <[b6]>; Duncan, Ken

<[b6]>; Fernandes, Prabhavathi <[b6]>; Fessel, Josh (NIH/NHLBI)

[E] <[b6]>; Gatto, Greg <[b6]>; Grobler, Jay <[b6]>; Hewitt, Judith

(NIH/NIAID) [E] <[b6]>; Jonson, Samantha (NIH/NCATS) [E] <[b6]>; Lutz, Cat

<[b6]>; Nestle, Frank <[b6]>; Ottinger, Elizabeth (NIH/NCATS) [E]

APAR0000004869

[b6] Parker, Ashley (NIH/OD) [E] [b6] Payne, David
[b6] Qashu, Felicia (NIH/OD) [E]
[b6] Rao, Srinivas [b6] Rappaport, Jay [b6]
Stegmeier, Frank [b6]; Young, John [b6]
Cc: Alvarez, Rosa Maria <rosalvarez@deloitte.com>
Subject: RE: Slides and document from our meeting

Joe et Al.,

I added few sugg/revs for your consideration

Thank you,

Tony

Antonello Punturieri, M.D., Ph.D.
Program Director, COPD and Environment Division of Lung Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
6705 Rockledge Drive, 403K MSC 7952
Bethesda, MD 20892

T [b6]
[b6]

COVID-19

Get the latest public health information from CDC: <https://www.coronavirus.gov>

Get the latest research information from NIH: <https://grants.nih.gov/policy/natural-disasters/corona-virus.htm>



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the Division of Lung Diseases*

From: Menetski, Joseph (FNIH) [T] [b6]

Sent: Tuesday, May 12, 2020 3:44 PM

To: Adams, Peter (OS/ASPR/BARDA) [b6]; Anderson, Annaliesa [b6]
Baric, Ralph [b6]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E]
[b6]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E]
[b6]; Deming, Damon (FDA/CDER) [b6]; Diamond, Michael
[b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi
[b6]; Fessel, Josh (NIH/NHLBI) [E] [b6]; Gatto, Greg [b6]
Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [b6]; Jonson, Samantha
(NIH/NCATS) [E] [b6]; Lutz, Cat [b6]; Nestle, Frank [b6];
Ottinger, Elizabeth (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI)
[E] [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Rao, Srinivas

[b6] Rappaport, Jay [b6] Stegmeier, Frank [b6]
Young, John [b6]
Cc: Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Menetski, Joseph (FNIH) [T] [b6]
Subject: Slides and document from our meeting

Dear Preclinical Working group,

Thank you for another terrific call. I am attaching the slides we showed that contain the future state strategy slide. Also, I have attached the Request for information/Information for prioritization form. As discussed, please make suggestions and modifications. The questions about "what is the metric?" are to you, please suggest the appropriate metric for that category.

Please try to have your responses to me by COB tomorrow and we will be able to review on Friday.

Sincerely,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
[b6] fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/12/2020 9:27:44 PM
To: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.ema]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
CC: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Subject: RE: Slides and document from our meeting
Attachments: DPI CoV-2 ACTIVE slides May 2020_KRB2.pptx

One more file from today. Here are Matt's slides about the Open Science Portal.

Best,
Joe

From: Menetski, Joseph (FNIH) [T]
Sent: Tuesday, May 12, 2020 3:44 PM
To: Adams, Peter (OS/ASPR/BARDA) [b6]; Anderson, Annaliesa [b6]; Baric, Ralph [b6]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E]; Cihlar, Tomas [b6]; Colvis, Christine [b6]; Deming, Damon (FDA/CDER) [b6]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith [b6]; Jonson, Samantha (NIH/NCATS) [E]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Liz [b6]; Parker, Ashley (NIH/OD) [E]; Payne, David [b6]; Punturieri, Antonello (NIH/NHLBI) [E]; Qashu, Felicia [b6]; Rao, Srinivas

[b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]
Young, John [b6]
Cc: Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Menetski, Joseph (FNIH) [T] [b6]
Subject: Slides and document from our meeting

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Please try to have your responses to me by COB tomorrow and we will be able to review on Friday.

Sincerely,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
[b6] | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Rappaport, Jay [b6]
Sent: 5/11/2020 1:50:59 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Stegmeier, Frank [b6]; Young, John [b6]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: Re: Request for change: ACTIV Preclinical working group (Tuesday meeting)

DearJoe and All,

This would be great for me and allow me and other NPRC Directors, to attend both ACTIV and NPRCs meetings. Thank you for making this change.

Best regards,

Jay

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From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Monday, May 11, 2020 8:21:44 AM
To: Adams, Peter (OS/ASPR/BARDA) [b6]; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa [b6]; Baric, Ralph [b6]; Carter, Kara [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Deming, Damon (FDA/CDER) [b6]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Payne, David [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]
Subject: RE: Request for change: ACTIV Preclinical working group (Tuesday meeting)

External Sender. Be aware of links, attachments and requests.

Dear all,

Thanks to all that replied quickly. The current suggested time will not work for all, so I will continue to try to move them meeting. For now, we will keep the Tuesday time, but look for a permanent new time starting next week.

Joe

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Monday, May 11, 2020 9:00 AM
To: Adams, Peter (OS/ASPR/BARDA) [b6]; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa [b6]; Baric, Ralph [b6]; Carter, Kara [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Deming, Damon (FDA/CDER) [b6]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Payne, David [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]
Subject: Request for change: ACTIV Preclinical working group (Tuesday meeting)

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We would like additional involvement in the working group by the NPRCs and this would allow Jay to attend both and potentially others to attend our meeting.

Please let me know if this would be an impossible change.

Sincerely,

Joe

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

[b6] fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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APAR0000004881



From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/11/2020 1:21:44 PM
To: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosa.varez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payne, David [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: Request for change: ACTIV Preclinical working group (Tuesday meeting)

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Joe

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Sent: Monday, May 11, 2020 9:00 AM
To: Adams, Peter (OS/ASPR/BARDA) [b6]; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa [b6]; Baric, Ralph [b6]; Carter, Kara [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Deming, Damon (FDA/CDER) [b6]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Payne, David [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]
Subject: Request for change: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group,

APAR0000004882

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Joe

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Prabha Fernandes [b6]
Sent: 5/11/2020 1:13:38 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Alvarez, Rosa' [rosalvarez@deloitte.com]; 'Anderson, Annaliesa' [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; 'Carter, Kara' [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; 'Diamond, Michael' [b6]; 'Duncan, Ken' [b6]; 'Gatto, Greg' [b6]; 'Grobler, Jay' [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; 'Lutz, Cat' [b6]; 'Nestle, Frank' [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; 'Payne, David' [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Rao, Srinivas' [b6]; 'Rappaport, Jay' [b6]; 'Stegmeier, Frank' [b6]; 'Young, John' [b6]
Subject: RE: Request for change: ACTIV Preclinical working group (Tuesday meeting)

Hello Joe,
This week I cannot do it but from next week I can.
Regards,
Prabha

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Monday, May 11, 2020 9:00 AM
To: Adams, Peter (OS/ASPR/BARDA) [b6]; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa [b6]; Baric, Ralph [b6]; Carter, Kara [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Deming, Damon (FDA/CDER) [b6]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Payne, David [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]
Subject: Request for change: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group,

This meeting overlaps (every week) the NPRC Directors meeting. I am writing to ask if we could move this meeting from Tuesday 2-3pm to **Wednesday 12-1pm**? Would it be possible to make this change permanently?

We would like additional involvement in the working group by the NPRCs and this would allow Jay to attend both and potentially others to attend our meeting.

Please let me know if this would be an impossible change.

Sincerely,

Joe

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

b6 fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/11/2020 12:28:18 AM
To: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiJP]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Subject: Public preclinical compounds to assess for initial prioritization scheme
Attachments: Preclinical Asset filter strategy.pptx; Preclinical assets from public databases.xlsx

Dear All,

I have spent a little time with the list of therapies that Deloitte has collected by scraping several public databases. I have done an initial filtering exercise and thought you might like to see the initial list. We may use this as a test for how we might prioritize therapies as we get into this more.

I have included an excel sheet based on slide 7 and shown graphically on slides 8 and 9.

We can discuss more on Monday.

Best regards,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health

[b6] fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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APAR0000004885



From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/9/2020 7:20:42 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: ACTIV emails

OK, thank you. Then I am good.

Joe

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Saturday, May 9, 2020 2:54 PM
To: Menetski, Joseph (FNIH) [T] [b6]
Subject: RE: ACTIV emails

Hi Joe,

I've shared these with David every Friday – they include all of the inquiries we have received since the launch of ACTIV and include a black header showing the week in which they were obtained.

This is everything we received for preclinical but feel free to browse through the other tabs for clinical Tx ect., you may see something that may apply to your working group.

Best,
Ashley

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Saturday, May 9, 2020 2:18 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV emails

Hi Ashley,

Thank you. Sorry to bug you on a weekend.

Are there files from previous weeks, or does this include everything that OD has gotten so far?

We are trying to collect data for prioritization in the preclinical space and I want to make sure I am not missing anything. You can send them Monday, not an urgent request.

Thank you for your reply and collecting all this.

Best,

Joe

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Saturday, May 9, 2020 2:13 PM
To: Menetski, Joseph (FNIH) [T] [b6]
Subject: Re: ACTIV emails

Hi Joe,

I resent the excel file in a separate email from my iPhone.

Best,
Ashley

On May 9, 2020, at 12:56 PM, Menetski, Joseph (FNIH) [T] b6 wrote:

Dear Ashley,

I was hoping that you could resend the excel files that contain the emails to NIH from the last few weeks? I would like to recheck and make sure I have all the preclinical information that I need for moving forward in the preclinical prioritization group. What ever is easiest for you would be terrific.

Thank you for collecting these and I appreciate your sending these.

Thank you,

Joe

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

b6 fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

<image001.jpg> <image002.jpg> <image003.jpg> <image004.jpg>

Donate to the FNIH's Pandemic Response Fund to combat COVID-19 fnih.org/pandemic

<image005.png>

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/9/2020 5:50:34 PM
To: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]
Subject: FW: Clarification

Dear Preclinical Working group members,

Please see the email below. Annaliesa promised to ask Dr Dolsten for some clarification about his chat comment during the Leadership Team Meeting and she provides that explanation below.

This maybe a interesting topic to discuss with our expert panels as they are deciding on prioritization of preclinical therapies.

Thank you Annaliesa!

Best,
Joe

From: Anderson, Annaliesa [b6]
Sent: Saturday, May 9, 2020 1:36 PM
To: Menetski, Joseph (FNIH) [T]; [b6]
Subject: Clarification

Hi Joe

I followed up with Mikael Dolsten regarding his question to the preclinical group:

"Can the team suggest what types of experiments would provide broader learnings just than single drug or vaccine? such as creating learnings cross many products"

What triggered the question was the suggestion to test a CCR2/5 inhibitor . This drug class that failed for a several of human conditions and there are limited biological learnings, as many different cells are partly impacted. Thus how we can recommend the testing of different drugs/ modalities to provide information on the different cytokine networks , signaling pathways , cell types that they target. For example Baricitinib (JAKi) has been tested; there are other JAKis that target different pathways. How would they compare? In addition when looking at these compounds in the models, what are the readouts that should be considered to get a more systematic systems biology approach to test biological concepts and not just having shots in the dark.

Please can you share this with the group.
Thank you
Liesa

Comments during the call

annaliesa, yes that would be great. I believe, appropriately so, the focus of ACTIV we are involved with have been toward a Therapeutic or Vaccine. Perhaps he is thinking more from a pathogenetic mechanism of various "syndrome" features to include cardiac involvement, potentially vasculitis, Immune response characterization to infection etc etc. Makes sense to me. I bet many of the intra and extamural grants will be aimed at this as well. Srin.

Considering different targets (eg viral vs. host and disease pathology targets , a one size fits all is not god. Since 2 or more drugs may be needed in therapy of these patients. For each of these targets we could come up with best profile.. Prabha

I think the samples from the studies, that are not used, can be made available as part of a sample bank for further studies regarding the clinical and animal models and also defining better what is working and what isn't. It would be worth collecting samples for plasma and RNAseq etc. Such mechanistic information could help define synergies and combinations

Animal studies - samples would be helpful.I. Human studies are not "pure" as all patients are getting more than one drug.. Prabha

Annaliesa S Anderson Ph.D. FAAM

Chief Scientific Officer Bacterial Vaccines

Chief Scientific Officer Hospital Business Unit

Pfizer Vaccine Research and Development, Bldg 222, Rm 3184

401 N Middletown Road | Pearl River | NY 10965| USA |

Tel: [b6] Mobile: [b6] Fax: (845) 474-5150

[b6]

From: Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC]
Sent: 5/6/2020 2:24:51 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Young, John [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; [b6]; Gatto, Gregory [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Stratton, Benjamin [bstratton@DELOITTE.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D [b6]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6]
CC: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payne, David [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Stegmeier, Frank [b6]
Subject: Re: ACTIV Animal Model Sub Group PRECLINICAL-TX Meeting

All –

It's been pointed out that I listed Rhesus twice. My mistake. It should read...

By far, Rhesus is the furthest along, followed by AGM and then Cynos. I continue to update this slide deck when new data comes to my attention.

Thanks –

Clint

From: "Florence, Clint (NIH/NIAID) [E]" [b6]
Date: Wednesday, May 6, 2020 at 9:38 AM
To: "Menetski, Joseph (FNIH) [T]" [b6]; "Ottinger, Elizabeth (NIH/NCATS) [E]" [b6]; "Alvarez, Rosa Maria" <rosalvarez@deloitte.com>; "Young, John"

[REDACTED] b6, "Hewitt, Judith (NIH/NIAID) [E]" [REDACTED] b6, "Gatto, Gregory" [REDACTED] b6, "Colvis, Christine (NIH/NCATS) [E]" [REDACTED] b6, "Stratton, Benjamin" <bstratton@DELOITTE.com>, "Wholley, David (FNIH) [T]" [REDACTED] b6, "Rodriguez, Robin D" [REDACTED] b6, "Deming, Damon (FDA/CDER)" [REDACTED] b6, "Srinivas.Rao@sanofi.com" [REDACTED] b6, "Carter, Kara" [REDACTED] b6, "Colvis, Christine (NIH/NCATS) [E]" [REDACTED] b6, "Diamond, Michael" [REDACTED] b6, "Duncan, Ken" [REDACTED] b6, "Fernandes, Prabhavathi" [REDACTED] b6, "Grobler, Jay" [REDACTED] b6, "Hewitt, Judith (NIH/NIAID) [E]" [REDACTED] b6, "Jonson, Samantha (NIH/NCATS) [E]" [REDACTED] b6, "Nestle, Frank" [REDACTED] b6, "Ottinger, Elizabeth (NIH/NCATS) [E]" [REDACTED] b6, "Parker, Ashley (NIH/OD) [E]" [REDACTED] b6, "Payne, David" [REDACTED] b6, "Qashu, Felicia (NIH/OD) [E]" [REDACTED] b6, "Stegmeier, Frank" [REDACTED] b6

Subject: Re: ACTIV Animal Model Sub Group PRECLINICAL-TX Meeting

All –

Please see attached slide deck which summarizes NHP model development to date that I know about worldwide.

By far, Rhesus is the furthest along, followed by Cynos and then Rhesus. I continue to update this slide deck when new data comes to my attention.

Thought this might be interest and useful. If desired, I can present at a meeting.

Thanks –

Clint

From: "Menetski, Joseph (FNIH) [T]" [REDACTED] b6
Date: Wednesday, May 6, 2020 at 8:12 AM
To: "Ottinger, Elizabeth (NIH/NCATS) [E]" [REDACTED] b6, "Alvarez, Rosa Maria" <rosalvarez@deloitte.com>, "Young, John" [REDACTED] b6, "Hewitt, Judith (NIH/NIAID) [E]" [REDACTED] b6, "Gatto, Gregory" [REDACTED] b6, "Colvis, Christine (NIH/NCATS) [E]" [REDACTED] b6, "Stratton, Benjamin" <bstratton@DELOITTE.com>, "Wholley, David (FNIH) [T]" [REDACTED] b6, "Rodriguez, Robin D" [REDACTED] b6, "Deming, Damon (FDA/CDER)" [REDACTED] b6, "Florence, Clint (NIH/NIAID) [E]" [REDACTED] b6, "Carter, Kara" [REDACTED] b6, "Colvis, Christine (NIH/NCATS) [E]" [REDACTED] b6, "Diamond, Michael" [REDACTED] b6, "Duncan, Ken" [REDACTED] b6, "Fernandes, Prabhavathi" [REDACTED] b6, "Grobler, Jay" [REDACTED] b6, "Hewitt, Judith (NIH/NIAID) [E]" [REDACTED] b6, "Jonson, Samantha (NIH/NCATS) [E]" [REDACTED] b6, "Menetski, Joseph (FNIH) [T]" [REDACTED] b6, "Nestle, Frank" [REDACTED] b6, "Ottinger, Elizabeth (NIH/NCATS) [E]" [REDACTED] b6, "Parker, Ashley (NIH/OD) [E]" [REDACTED] b6, "Payne, David" [REDACTED] b6, "Qashu, Felicia" [REDACTED] b6

(NIH/OD) [E] [b6] "Stegmeier, Frank" [b6]

Subject: RE: ACTIV Animal Model Sub Group PRECLINICAL-TX Meeting

Dear All,

This is a terrific presentation (my opinion) and contains a lot of data.

Thank you Liz for sharing.

Joe

From: Ottinger, Elizabeth (NIH/NCATS) [E] [b6]

Sent: Tuesday, May 5, 2020 3:08 PM

To: Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Young, John [b6]

[b6] Hewitt, Judith (NIH/NIAID) [E] [b6] Gatto, Gregory

[b6] Colvis, Christine (NIH/NCATS) [E] [b6] Menetski, Joseph (FNIH) [T]

[b6] Stratton, Benjamin <bstratton@DELOITTE.com>; Wholley, David (FNIH) [T] [b6]

Rodriguez, Robin D [b6] Deming, Damon (FDA/CDER)

[b6]; Florence, Clint (NIH/NIAID) [E] [b6]

Subject: RE: ACTIV Animal Model Sub Group PRECLINICAL-TX Meeting

Attached is presentation that Lovelace gave yesterday with some animal information. Also, wanted to provide the information for the NIH COVID Digital Pathology Repository (COVID-DPR) <https://COVID19pathology.nih.gov> where patient samples are being deposited. Contact information is on the site and to request access to view. Could be useful if animal pathology data could also be deposited.

Regards,

Liz

From: Alvarez, Rosa Maria <rosalvarez@deloitte.com>

Sent: Tuesday, May 5, 2020 10:18 AM

To: Young, John [b6]; Hewitt, Judith (NIH/NIAID) [E]

[b6] Gatto, Gregory [b6] Colvis, Christine (NIH/NCATS) [E]

[b6] Menetski, Joseph (FNIH) [T] [b6] Ottinger, Elizabeth (NIH/NCATS) [E]

[b6]; Stratton, Benjamin <bstratton@DELOITTE.com>; Wholley, David (FNIH) [T]

[b6]; Rodriguez, Robin D [b6] Deming, Damon

(FDA/CDER) [b6] Florence, Clint (NIH/NIAID) [E]

[b6]

Subject: RE: ACTIV Animal Model Sub Group PRECLINICAL-TX Meeting

Hi all,

Thank you again for your time yesterday. The key action item coming out of our meeting was to finalize our small animal inventory (attached). See below for additional details on this process:

[5/6 - Clint and Judy] Take first pass at identifying and filling in the gaps of the Animal Model inventory, including questions that will be answered with the specific animal models (e.g. infectivity, transmission, extent of disease presentation [mild, severe], etc.). Share with Sub Group on 5/6 for additional feedback

[5/7 - Sub Group] Identify and fill out gaps of the animal model inventory (as described above) for discussion during our Sub Group Meeting

[5/7 - Meeting] – we are trying to postpone our meeting to Thursday to allow for more time work on the animal model inventory

Regards,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: [REDACTED]
www.deloitte.com

From: Alvarez, Rosa Maria

Sent: Sunday, May 3, 2020 10:51

To: Young, John [REDACTED]; Hewitt, Judith (NIH/NIAID) [E]
[REDACTED] Gatto, Gregory [REDACTED] Colvis, Christine (NIH/NCATS) [E]
[REDACTED] Menetski, Joseph (FNIH) [T]; [REDACTED] Ottinger, Elizabeth (NIH/NCATS) [E]
[REDACTED] Stratton, Benjamin <bstratton@DELOITTE.com>; [REDACTED] Rodriguez, Robin D
[REDACTED] Deming, Damon (FDA/CDER) [REDACTED]
[REDACTED] Florence, Clint (NIH/NIAID) [E] [REDACTED]

Subject: RE: ACTIV Animal Model Sub Group PRECLINICAL-TX Meeting

Hi all,

Hope you had a good weekend. Please see below for our agenda for tomorrow's session.

We will kick-off our meeting discussing our latest version of the Animal Model inventory (attached). Thank you all who contributed entries to this inventory.

Let us know if you have any questions.

Agenda Topic	Duration	Facilitator
Review and discuss updated small animal inventory	30 min	Sub Group
Provide update on AWS conversation regarding preclinical data sharing platform	10 min	Cat Lutz, Christine Colvis
Discuss final NHP Strategy slides	10 min	Jay Rappaport
Align on Next Steps	10 min	Joe Menetski, Rosa Alvarez

Regards,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: [REDACTED]
www.deloitte.com

-----Original Appointment-----

From: Alvarez, Rosa Maria

Sent: Thursday, April 23, 2020 10:31 AM

To: Young, John; Alvarez, Rosa Maria [REDACTED] Hewitt, Judith (NIH/NIAID) [E]; [REDACTED] Gatto,

Gregory; Colvis, Christine (NIH/NCATS) [E]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS [E]; Stratton, Benjamin; [b6] Rodriguez, Robin D; [b6] Deming, Damon (FDA/CDER);

[b6]

Cc: Florence, Clint (NIH/NIAID) [E]

Subject: ACTIV Animal Model Sub Group PRECLINICAL-TX Meeting

When: Monday, May 4, 2020 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://deloitte.zoom.us/j/91812121212> [b6]



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Password:

Phone one-tap:

[b6]

Join by Telephone

Dial:

Meeting ID:

Password:

[b6]

International numbers

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APAR0000004894

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/1/2020 6:30:00 PM
To: [REDACTED] b6
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: ACTIV partnership for COVID-19
Attachments: FNIH Covid 19 meeting April 03 2020 notes.docx

Dr. Louise Pitt
Director, Center for Aerobiological Sciences
USAMRIID

Dear Dr. Pitt,

I am writing to you at the suggestion of Brigadier General Michael Talley. As you know well, addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. While the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond, the field needs to find a way to focus and prioritize these many efforts, as there is a critical need for effective treatments and vaccines.

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and of course working with other government agencies and individual companies on accelerated testing of vaccines and therapeutics. In order to broaden the response on April 17 we announced ACTIV, a new public-private partnership with FDA, BARDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics. We have since added representatives from the Veterans Administration and, in recognition of the valuable work and capabilities of the DoD in these and other fields of medical research, approached BG Talley earlier this week to see if there would be interest in adding representatives from the Department to our partnership.

As described in the attached meeting notes (from our kick-off on April 3) we have now set up Working Groups to decide efforts in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development. At the suggestion of BG Talley, I would like to invite you to join as a member on the Therapeutics – Preclinical Working Group which is being co-chaired by Christine Colvis, NCATS and John Young, Roche. While this group has been meeting for several weeks, there are many decisions still to be made and many areas of discussion that can benefit from your insights and expertise.

Please direct your response to this invitation to Joe Menetski, [REDACTED] b6 of the Foundation for the NIH, who will fill you in on the mission and progress of the Working Group and get you integrated into meeting logistics. I look forward to your contributions to this critical effort.

Best,
Francis Collins

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/1/2020 4:11:20 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: DoD invitation note #3: Dr. Louise Pitt for TX - Preclinical WG
Attachments: ACTIV Partnership Leadership Meeting QA Follow Up_20200424 final.docx

Francis and Ashley:

Note for Dr. Louise Pitt
Director, Center for Aerobiological Sciences
USAMRIID

Email: [REDACTED] b6

Dr. Louise Pitt
Director, Center for Aerobiological Sciences
USAMRIID

Dear Dr. Pitt,

I am writing to you at the suggestion of Brigadier General Michael Talley. As you know well, addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. While the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond, the field needs to find a way to focus and prioritize these many efforts, as there is of course a critical need for effective treatments and vaccines.

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Please direct your response to this invitation to Joe Menetski, [REDACTED] b6 of the Foundation for the NIH, who will fill you in on the mission and progress of the Working Group and get you integrated into meeting logistics. I look forward to your contributions to this critical effort.

Best,

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 4/27/2020 10:03:31 PM
To: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiJP]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Subject: FW: Q re COVID NHPs

Thank you for the link Sheri.

Dear Working group,

Sheri told us that there was a forum for sharing animal model data. The link below is that forum. Please take a look and let's use this as an example of what is out there and if it would suit the needs of the animal models subgroup.

Best,
Joe

From: Hild, Sheri (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 5:24 PM
To: Colvis, Christine (NIH/NCATS) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: RE: Q re COVID NHPs

Sorry got side-tracked. Here is the open data sharing portal: <https://openresearch.labkey.com/Coven/project-begin.view?>

Most everyone is doing bioRxiv preprints too, so data are available.

Sheri

From: Colvis, Christine (NIH/NCATS) [E] [b6]
Sent: Monday, April 27, 2020 1:47 PM

To: Hild, Sheri (NIH/OD) [E] [b6]

Subject: FW: Q re COVID NHPs

This is the kind of thing we need for ACTIV. Can this be shared with the ACTIV group...at least the animal model subgroup?

From: Anderson, James (NIH/OD) [E] [b6]

Sent: Monday, April 27, 2020 10:42 AM

To: Austin, Christopher (NIH/NCATS) [E] [b6]

Subject: RE: ACTIV Daily Update 20200427.pptx

Chris,

Are you (Christine Colvis) learning what you need about NHP resources? Two weeks ago I asked the NPRC Directors to create an inventory of their resources that could be used for COVID research, Tables 1 and 2. We told them that ACTIV is their top priority for now. I can't tell who is talking to whom. If you need to know anything about NHP or be connected with the NPRCs please don't hesitate to ask. We also have contacts across the federal government on a Trans-federal NHP planning WG.

Jim

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 4/23/2020 4:52:28 PM
To: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Gatto, Greg [b6]; Grobler, Jay [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiJP]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [b6]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
CC: Kirby, Donna [b6]; Lombardo, John [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Moore, Debra [b6]
Subject: Final Slide deck from yesterday's Leadership Team Meeting
Attachments: ACTIV Partnership Leadership Team Meeting 20200421 Final 2.pptx

Dear Preclinical Working group,

I am sharing the slides that were presented to the Leadership team yesterday to highlight the progress of the effort. The leadership team felt the effort was going very well and will be meeting again in 2 weeks.

The progress is outstanding and is expected to continue at least as fast, so we still have work to do. Thank you for all of your input and efforts so far.

Best regards,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
[b6] fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19. fnih.org/pandemic

APAR0000004907



From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 2/1/2021 5:23:27 PM
To: Young, John [b6]; Charette, Marc (NIH/NHLBI) [E]
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E]
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Rodriguez, Robin D
[b6] Ottinger, Elizabeth (NIH/NCATS) [E] [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine
(NIH/NCATS) [E] [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T]
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Colvis, Christine
(NIH/NCATS) [E] [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6]
[b6] Nancy Haigwood [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6]
USARMY MEDCOM USAMRIID (USA); [b6] Florence, Clint
(NIH/NIAID) [E] [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Anderson, James
(NIH/OD) [E] [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley
(NIH/OD) [E] [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gatto, Gregory
[b6]; Jonson, Samantha (NIH/NCATS) [E] [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connelly, Sarah
[o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]
CC: Lumsden, Joanne (NIH/NCATS) [C] [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]
Subject: ACTIV Preclinical - In Vivo Strategy Notes
Attachments: 2021029_ACTIV Preclinical_In Vivo Strategy_Notes.docx

Hi all,

Please find the notes from Friday's meeting attached. Let us know if you have any suggested modifications.

Best,
Harrison

-----Original Appointment-----

From: Hawk, Harrison
Sent: Friday, October 16, 2020 2:06 PM
To: Young, John; [b6] Hild, Sheri (NIH/OD) [E]; Rodriguez, Robin D; Ottinger, Elizabeth (NIH/NCATS) [E]; Hawk, Harrison; [b6] Menetski, Joseph (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; [b6] Nancy Haigwood; [b6]
[b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Florence, Clint (NIH/NIAID) [E]; [b6] Parker, Ashley (NIH/OD) [E]; Gatto, Gregory; Jonson, Samantha (NIH/NCATS) [E]; Connelly, Sarah
Cc: Lumsden, Joanne (NIH/NCATS) [C]
Subject: ACTIV Preclinical - In Vivo Strategy
When: Friday, January 29, 2021 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where:

Hi all,

Please see below for the agenda for this morning's meeting.

Agenda Topic	Duration	Facilitator
Updates on offline NHP field guide work	5 mins	Nancy Haigwood Jay Rappaport
Updates on b5 production (as needed)	5 mins	Clint Florence
Discuss possible topics for small animal models and NHP panels	30 minutes	Christine Colvis Joe Menetski
Align on action items and next steps	5 mins	Sarah Connelly Joe Menetski



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From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 1/15/2021 7:47:39 PM
To: [b6] Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto, Gregory [b6]; Young, John [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Rodriguez, Robin D [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6]
Subject: RE: Data Portal Implementation
Attachments: 20210114_ACTIV Preclinical_Data Portal Implementation_Notes.docx

Hi everyone,

Please find the notes from yesterday's meeting attached.

Best,
Harrison

Harrison Hawk
Deloitte Consulting LLP
Mobile: [b6]
www.deloitte.com

-----Original Appointment-----

From: Hawk, Harrison
Sent: Wednesday, January 13, 2021 2:54 PM
To: [b6] Connelly, Sarah; Hewitt, Judith (NIH/NIAID) [E]; [b6] Gatto, Gregory; Young, John; Colvis, Christine (NIH/NCATS) [E]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS) [E]; Rodriguez, Robin D; Jonson, Samantha (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Mason, Stephen
Subject: Data Portal Implementation
When: Thursday, January 14, 2021 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://deloitte.zoom.us/j/[b6]

Hi all,

Please see the agenda for tomorrow's data portal implementation meeting below. Let us know if you have any suggested modifications.

APAR0000004928

Best,
Harrison

Agenda Topic	Duration	Facilitator
New animal model webpage updates	10 mins	Samantha Jonson
Discuss new additions to page (including the viral reference strain recommendation criteria, mouse model literature)	20 mins	Samantha Jonson
Updates on the NHP study-level data portal	10 mins	Jay Rappaport



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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 12/23/2020 10:51:07 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: Proposal for a national tracking, testing, and reporting of emergent SARS-CoV-2 variants
Attachments: ACTIV_Preclinical_Emerging Sequence Surveillance Proposal_F3.docx

Dear All,

Thank you for your comments and feedback. This version has fixed a typo, changing the last summary budget table to 2023 (thanks Chris).

Please feel free to share as suggested. Again, let me know if there are any questions or suggestions.

Best regards,
Joe

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Wednesday, December 23, 2020 1:35 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]
Subject: RE: 12/23 war room slides

Dear All,

Maria and David suggested that I send the current version of the Emerging Variant proposal to all of you as we will be discussing it this afternoon.

Please let me know if you have any questions, so that I might be able to connect with the team if needed.

Best regards,
Joe

APAR0000004930

From: Wholley, David (FNIH) [T] <[b6]>

Sent: Wednesday, December 23, 2020 12:10 PM

To: Collins, Francis (NIH/OD) [E] <[b6]>; Tabak, Lawrence (NIH/OD) [E] <[b6]> Lane, Cliff (NIH/NIAID) [E] <[b6]>; Freire, Maria (FNIH) [T] <[b6]>; Austin, Christopher (NIH/NCATS) [E] <[b6]>; Parker, Ashley (NIH/OD) [E] <[b6]>; Anderson, James (NIH/OD) [E] <[b6]>; Patterson, Amy (NIH/NHLBI) [E] <[b6]>

Cc: Menetski, Joseph (FNIH) [T] <[b6]>

Subject: 12/23 war room slides

Please see attached the slides for our war room today at 5:30 PM, Wednesday, December 23. Joe Menetski will be joining us for the first half of the meeting to discuss the variant testing proposal.

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

<[b6]>

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 12/23/2020 7:26:26 PM
To: Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6] Cat.Lutz@jax.org; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]

Subject: Canceled: ACTIV Preclinical - In Vivo Strategy

Location: <https://deloitte.zoom.us/j/92010100000> [b6]

Start: 1/1/2021 3:00:00 PM

End: 1/1/2021 4:00:00 PM

Show Time As: Free

Recurrence: (none)

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 11/25/2020 9:34:22 PM
To: [b6]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; [b6]
[b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai];
[b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
[b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];
[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [b6]; CIV USARMY MEDCOM USAMRIID (USA) [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiena]; Mason, Stephen [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; [b6]
[b6] Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]
Subject: RE: ACTIV Preclinical full working group
Attachments: PRECLINICAL_Working Group_Agenda_20201125_v1.pptx; 11.19 ACTIV Leadership Team Meeting 20201118_vF.pdf

Dear Preclinical working group,

Please find attached the slides from today's meeting and from the LT meeting last Thursday. Please feel free to send me any thoughts or questions about either of these.

As I mentioned at the meeting, please keep these to ACTIV business, they are not meant for distribution.

Best regards,
Joe

From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 12/23/2020 5:37:08 PM
To: Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]

Subject: ACTIV Preclinical - In Vivo Strategy

Location: <https://deloitte.zoom.us/j/92076952920> [b6]

Start: 10/23/2020 2:00:00 PM

End: 10/23/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: (none)

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From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 12/14/2020 10:37:37 PM
To: Young, John [b6], Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto, Gregory [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Rodriguez, Robin D [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6]
Subject: RE: Data Portal Implementation
Attachments: 20201210_ACTIV Preclinical_Data Portal Implementation Notes.docx

Hi all,

Please see attached for notes from our meeting on 12/10. Let me know if you have any suggested additions or modifications.

Best,
Harrison

Harrison Hawk
Deloitte Consulting LLP
Mobile: [b6]
www.deloitte.com

-----Original Appointment-----

From: Hawk, Harrison
Sent: Thursday, October 15, 2020 5:33 PM
To: [b6] Young, John; Hawk, Harrison; Connelly, [b6] Hewitt, Judith (NIH/NIAID) [E]; [b6] Gatto, Gregory; Colvis, Christine (NIH/NCATS) [E]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS) [E]; Rodriguez, Robin D; Jonson, Samantha (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Mason, Stephen
Subject: Data Portal Implementation
When: Thursday, December 10, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

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From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 11/16/2020 9:26:50 PM
To: Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; [b6]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto, Gregory [b6]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D [b6] Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6]
Subject: RE: Data Portal Implementation
Attachments: 20201113_ACTIV Preclinical_Data Portal Implementation_Notes_vF.docx

Hi all,

Please find the notes from our meeting on 11/12 attached. Let us know if you suggest modifications.

Thanks,
Harrison

-----Original Appointment-----

From: Hawk, Harrison
Sent: Wednesday, November 11, 2020 6:13 PM
To: Connelly, Sarah; [b6] Hewitt, Judith (NIH/NIAID) [E]; [b6] Gatto, Gregory; Young, John; Colvis, Christine (NIH/NCATS) [E]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS) [E]; [b6] Rodriguez, Robin D; Jonson, Samantha (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Mason, Stephen
Subject: Data Portal Implementation
When: Thursday, November 12, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

Hi all,

Please see below for the agenda for tomorrow's Data Portal Implementation meeting. Let us know ahead of time if you have any questions or would like to suggest modifications.

Thanks,
Harrison

Agenda Topic	Duration	Facilitator
New animal model webpage updates	10 mins	Samantha Jonson
Discuss new additions to page (including the viral reference strain recommendation criteria, mouse model literature)	20 mins	Samantha Jonson
Updates on the NHP study-level data portal	10 mins	Jay Rappaport



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v.E.1

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/29/2020 7:43:17 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: any word on how the meeting went today?

Oh yes, that's why I asked. thanks

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, April 29, 2020 3:41 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: any word on how the meeting went today?

Nothing as of yet. Did you see the note that Francis was no longer presenting ACTIV? The focus is only on vaccines.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, April 29, 2020 3:32 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: any word on how the meeting went today?

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/29/2020 1:19:52 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Update ACTIV Partner Slide

Thanks, everyone!

From: Wholley, David (FNIH) [T] { b6 }
Sent: Tuesday, April 28, 2020 8:13 PM
To: Gonzalez, Nina <ningonzalez@deloitte.com>
Cc: Collins, Francis (NIH/OD) [E] { b6 }; Parker, Ashley (NIH/OD) [E] { b6 }
Subject: RE: Update ACTIV Partner Slide

Formatting on the logos for BARDA and EMA looked a little off, so I fixed 'em.

From: Gonzalez, Nina <ningonzalez@deloitte.com>
Sent: Tuesday, April 28, 2020 7:57 PM
To: Wholley, David (FNIH) [T] { b6 }
Cc: Collins, Francis (NIH/OD) [E] { b6 }; Parker, Ashley (NIH/OD) [E] { b6 }
Subject: RE: Update ACTIV Partner Slide

Hi David —

See attached revised partner slide with addition of Nancy Messonnier from CDC.

Let me know if you need anything else.

Nina Gonzalez

Nina Gonzalez
Deloitte Consulting LLP
Tel/Direct: +1 202 748 6535
ningonzalez@deloitte.com | www.deloitte.com

Please consider the environment before printing

From: Wholley, David (FNIH) [T] { b6 }
Sent: Tuesday, April 28, 2020 7:38 PM
To: Gonzalez, Nina <ningonzalez@deloitte.com>
Cc: Collins, Francis (NIH/OD) [E] { b6 }; Parker, Ashley (NIH/OD) [E] { b6 }
Subject: [EXT] FW: Update ACTIV Partner Slide

Yes, forwarding to our engagement lead, Nina Gonzalez, to get this done.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 7:03 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Update ACTIV Partner Slide

Hi David,

Can the Deloitte team please update the partner slide to include CDC? Francis has already sent the slides forward for the WH briefing tomorrow but the logo and contact will need to be added for the presentation to Congress Thursday, 4/30. Can we have a updated version by tomorrow morning?

I'm attaching the most recent version.

Thank you,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, April 28, 2020 6:47 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: TIME SENSITIVE - WH Slides updated

I'm looking back at the ACTIV press release 4/17 and noticed we had CDC listed as a partner. Is there a reason for omitting them on the partner slide? Nancy Messonnier is the person we have representing CDC on the master list.

Thanks,
Ashley

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/28/2020 9:09:53 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: DoD Representatives

Given Ashley has answered you on this I assume she is working it. Let me know if I am mistaken.

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 5:05 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: DoD Representatives

Can I get this ASAP? Otherwise I'm going to miss the window for the WH slides.....

-----Original Message-----

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, April 28, 2020 4:31 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: FW: DoD Representatives

Can we quickly add Brigadier General Talley and DoD to the ACTIV roster slide? I'd like to be able to show we're connected -- BG Talley will be in the room tomorrow at the WH.

FC

-----Original Message-----

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Tuesday, April 28, 2020 4:26 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: DoD Representatives

BG Talley concurs with the following nominees to support the ACTIV initiative:

Executive Group: BG Talley (Dr. Dertzbaugh backup),

[b6]
Preclinical: Dr. Louise Pitt, USAMRIID, [b6]

Clinical: CAPT Tim Burgess, USUHS, [b6]

Vaccines: Dr. Nelson Michael, WRAIR, [b6]

From: Marston, Hilary (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB30660917B942FFBA9AE95D631116F3-MARSTONHD]
Sent: 4/28/2020 9:52:08 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: ACTIV background slides

Thanks Ashley!

On 4/28/20, 5:47 PM, "Parker, Ashley (NIH/OD) [E]" [b6] wrote:

Please see attached slides for Dr. Collins' WH briefing tomorrow -- slide 1 is a updated partnership slide.

Thanks,
Ashley

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] [b6]
Sent: Tuesday, April 28, 2020 11:20 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: ACTIV background slides

Sounds great to me, thanks.

On 4/28/20, 11:12 AM, "Parker, Ashley (NIH/OD) [E]" [b6] wrote:

Hi Hilary,

Sounds like a great plan. Please see attached slides that were presented at the ACTIV leadership meeting on 4/22. We are in the process of updating slide 2 to include additional partners -- I will share once this is ready.

It may be a good idea to keep the lines of communication open between OD and NIAID to share materials that are presented outside of NIH. If you agree -- we can be the POCs for cross sharing.

Thanks,
Ashley

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] [b6]
Sent: Tuesday, April 28, 2020 10:54 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: ACTIV background slides

Thanks Ashley - We anticipate future congressional hearings for ASF and want to make sure messaging is consistent with Dr. Collins. Even just the bullet points from the slides would be fine (and we can make our own visuals)

On 4/28/20, 10:12 AM, "Parker, Ashley (NIH/OD) [E]" [b6] wrote:

Hi Hilary,

We have slides that Francis has presented to the leadership group and we are editing a few slides for the WH briefing tomorrow. I think we can share some that we have but will need to know who will be using them and for what platform to ensure we are not duplicating.

Happy to chat if needed.

Thanks,
Ashley

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] [b6] v>
Sent: Tuesday, April 28, 2020 10:06 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: ACTIV background slides

Ashley, do you have slides that would fit the bill?

On 4/28/20, 10:05 AM, "Wholley, David (FNIH) [T]" [b6] wrote:

Hilary, could I ask that you please contact Ashley Parker in OD about this?

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E]

b6

Sent: Tuesday, April 28, 2020 9:24 AM

To: Wholley, David (FNIH) [T]

b6

Subject: ACTIV background slides

David do you have any ACTIV overview slides handy? For a lay audience that is new to the
PPP but savvy re COVID

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 9/17/2020 1:47:34 AM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: FW: OWS Board Materials
Attachments: 2020-09-18 OWS board briefing Vx Tx overview v 3.pdf; BLAZE-1 PR 9.16.20 FINAL pdf

FYI. Confidential as usual.

From: Morris, Katy (HHS/IOS) [b6]
Sent: Wednesday, September 16, 2020 7:15 PM
Subject: OWS Board Materials

A I,

Please see attached for OWS Board Materials.

Thank you,

Katy Covey Morris
Deputy Scheduler
The Department of Health and Human Services

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 9/13/2020 7:30:01 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabak]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: OWS Board Slides
Attachments: 2020-09-11 OWS board briefing Vx Tx overview Final.pdf; OWS Board Weekly (September 11 2020).pdf; 2020-09-10-2039- Moderna Ph3 current status - vF.pdf

Confidential, as usual.

From: Morris, Katy (HHS/IOS) [b6]
Sent: Sunday, September 13, 2020 3:10 PM
Subject: OWS Board Slides

Good Afternoon,

I hope you are having a great weekend! Please see attached for OWS Board Slides.

Sincerely,

Katy Covey Morris
Deputy Scheduler
The Department of Health and Human Services

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 9/3/2020 2:43:40 AM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: OWS Board Materials
Attachments: 2020-09-03 OWS board briefing Vx Tx overview v 1.pdf; OWS Board Weekly (September 03 2020).pdf; Slaoui.pdf

Confidential as usual. This time the meeting is on Thursday (tomorrow).

FC

From: Morris, Katy (HHS/IOS) : b6
Sent: Wednesday, September 2, 2020 10:36 PM
Subject: OWS Board Materials

A I,

Please see attached for OWS Board Materials.

Thank you,

Katy Covey Morris
Deputy Scheduler
The Department of Health and Human Services

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 8/28/2020 5:55:56 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: FW: OWS Board Slides
Attachments: 2020-08-28 OWS board briefing Vx Tx overview FINALv.2.pdf

FYI, not for distribution....

From: Morris, Katy (HHS/IOS) [b6]
Sent: Friday, August 28, 2020 1:50 PM
Subject: OWS Board Slides

Good Afternoon,

Please see attached for OWS Board Slides.

Have a great weekend,

Katy Covey Morris
Deputy Scheduler
The Department of Health and Human Services

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 8/21/2020 11:46:28 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: OWS Board presentation for later this morning
Attachments: 2020-08-21 OWS board briefing Vx Tx overview Final.pdf

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 8/15/2020 1:54:01 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: RE: OWS Board Update Slides

There was no real time meeting this week. That only happens on alternate weeks.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Saturday, August 15, 2020 9:24 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: Re: OWS Board Update Slides

Merk is listed as under consideration for ACTIV-2 — slide 9. Did the decision for them to pull out and run on their own come up at all?

Ashley

On Aug 15, 2020, at 9:03 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

FYI, as usual these are confidential

From: Morris, Katy (HHS/IOS) [b6]
Sent: Friday, August 14, 2020 4:13 PM
Subject: OWS Board Update Slides

Good Afternoon,

Please see attached for OWS Board Update Slides.

Have a great weekend,

Katy Covey Morris
Deputy Scheduler
The Department of Health and Human Services

<2020-08-14 OWS board briefing Vx Tx overview Final.pdf>

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 8/7/2020 1:15:11 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: today's OWS presentation -- confidential
Attachments: 2020-08-07 OWS board briefing Vx & Tx Final v.2.pdf

Here you go. Comments before 10 AM would be welcome.

FC

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 8/2/2020 4:57:21 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: OWS Board Update Slides
Attachments: OWS Board Weekly (July 31 2020).pdf; 2020-07-31 OWS board briefing Vx & Tx overview.pdf

FYI, worth looking at....

From: Morris, Katy (HHS/IOS) [b6]
Sent: Saturday, August 1, 2020 11:44 AM
Subject: OWS Board Update Slides

Good Morning,

Please see attached for OWS Board Update Slides.

Have a great weekend,

Katy Covey Morris
Deputy Scheduler
The Department of Health and Human Services

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 7/19/2020 7:57:25 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiyp]
Subject: FW: Weekly OWS Update
Attachments: OWS Board Weekly (July 17 2020)final.pdf; 2020-07-17 OWS board briefing Final.pdf

FYI and not for further distribution.

I'm puzzled by the reference in the second pdf about announcement of a contract with Pfizer next week. Huh?

FC

From: Tignor, Beth (HHS/IOS) [b6]
Sent: Sunday, July 19, 2020 10:20 AM
To: Tignor, Beth (HHS/IOS) [b6]
Cc: Morris, Katy (HHS/IOS) [b6]
Subject: Weekly OWS Update

Please find attached this week's update from the OWS Team.
Best wishes

*Beth Tignor
Director of Scheduling
The Department of Health and Human Services*

[b6]

Confidential and pre-decisional communication

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 7/24/2020 4:12:09 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: OWS
Attachments: OWS board briefing - 2020-07-22.pptx

So sorry, moving too fast...

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Friday, July 24, 2020 9:53 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: OWS

No attachment

From: Francis Collins [b6]
Date: Friday, July 24, 2020 at 9:51 AM
To: "Freire, Maria (FNIH) [T]" [b6], "Wholley, David (FNIH) [T]" [b6]
"Menetski, Joseph (FNIH) [T]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6]
"Austin, Christopher (NIH/NCATS) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6]
"Anderson, James (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: OWS

This just in. Not for distribution. I haven't reviewed yet. Meeting starts at 10 AM. Send me e-mail if you see something outrageous that I might want to comment on during the Board meeting.

FC

APAR0000005003

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 6/27/2020 6:19:54 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: got \$\$ for immunomodulator study

Thanks we have continued plans for the trial unabated and will be back in touch with Kevin about the funds.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Saturday, June 27, 2020 12:46 PM
To: Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: got \$\$ for immunomodulator study

Looks good.

From: Woodcock, Janet [b6]
Sent: Saturday, June 27, 2020 12:35 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: got \$\$ for immunomodulator study

Francis, you were fine. Yes we got the money agreed to and will aim to transfer it asap. As you may know, "they" are doling it out, not even sure who "they" are, but we had to give NIAID only \$206M as a down payment on the 2 studies and they fronted the rest from their funds, as the \$\$ are given out we will transfer them ASAP. Don't know when the next tranche comes but it should be soon, NCATS should start negotiations with the CROs etc. I will keep you posted. Lack of transparency frustrating but above my pay grade to solve. jw

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Saturday, June 27, 2020 11:46 AM
To: Woodcock, Janet [b6]
Subject: RE: got \$\$ for immunomodulator study

Hi Janet,

I hope you're getting a bit of a break to work in the garden today – but probably not as much as you'd like!

I understand you had a really productive conversation about the immunomodulators trial (aka ACTIV-1) with David Wholley and Stacey Adam yesterday. From David's report, I understand that your main concerns about the immunomodulators trial and the dexamethasone results have now been addressed, and we can move forward as soon as the protocol is approved – but I wanted to be sure that is correct. Once the protocol is approved, will there be a way for the funds to be rapidly transferred?

Thanks for all your help on this. I'm sorry if I sounded a bit frustrated on Thursday evening, it's been a tough week.

Best, Francis

From: Woodcock, Janet [b6]
Sent: Friday, June 26, 2020 12:20 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: got \$\$ for immunomodulator study

OK, use of background SOC does alter the situation for immunomodulators a bit. jw

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, June 26, 2020 7:00 AM
To: Woodcock, Janet [b6]
Subject: RE: got \$\$ for immunomodulator study

Hi Janet,

Spoke to Tony. He's looked at the Dex preprint, and thinks it is convincing. Cliff Lane has changed the clinical guidelines to include steroids as SOC for ventilated patients.

The Therapeutics Clinical WG has discussed the implications of the RECOVERY trial on at least three occasions and have developed a response that may not have been explained to you. David Wholley and Stacey Adams are planning to call you today to provide more information about that.

Best, Francis

From: Woodcock, Janet [b6]
Sent: Thursday, June 25, 2020 8:26 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: got \$\$ for immunomodulator study

Sure. I'm checking with FDA on their assessment of the dex arm of RECOVERY. You might ask Tony what he thinks if he has looked at the full paper. jw

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, June 25, 2020 7:48 PM
To: Woodcock, Janet [b6]
Subject: RE: got \$\$ for immunomodulator study

Thanks, Janet, that's reassuring, let's move ahead quickly and get this resolved.

Best, Francis

From: Woodcock, Janet [b6]
Sent: Thursday, June 25, 2020 6:58 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: got \$\$ for immunomodulator study

Well I think it is pretty straightforward. The funding is available. The landscape has changed though. The therapeutics working group did not have the advantage of the full description of the RECOVERY dexamethasone arm. It looks pretty solid to me. Neither the funders of the trial nor the sponsors of the trial can move forward until we are sure the design conforms to ethical principles. No matter what other groups have said, we (NCATS and OWS) will be responsible for this. So we have to take a close look at the RECOVERY results and decide if it is still ethical to randomize to a SOC that does not include dexamethasone, and if it does, how do we add immunomodulators? We can do this quickly and the money is available, but it must be done. NCAT might move forward with selecting a CRO while we work this out. jw

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, June 25, 2020 6:22 PM
To: Woodcock, Janet [b6]
Subject: RE: got \$\$ for immunomodulator study

Hi Janet,

I just got a message from Chris Austin (his summary is below, please tell me if this is not accurate). Now I am really confused about ACTIV-1 (the three immunomodulators). When Moncef was skeptical about the scientific basis for the choice of these three agents (on May 29, almost four weeks ago), we went through that in considerable detail, and he eventually agreed (or at least didn't object). You sent me a note a week ago (below) saying that the \$\$ had been allocated. So we moved ahead.

But now? I was disappointed that DAIT was not enthusiastic about the trial, but they are traditionally a rather academic group and didn't like the idea of having to do things this quickly and take risks that it might now work. So we moved quickly to identify a CRO model through NCATS and Duke, and that looked like the right way to get this done. ACTIV-1 has already taken longer to launch this than it should, so we were highly motivated to get it going. The Therapeutics WG already looked at the protocol, and my understanding is that the dex study did not change their view on how the study should be conducted (though I don't have the details on this).

I fear the companies are going to walk pretty soon if this doesn't get underway. The ACTIV Therapeutics WG will be deeply demoralized if this all blows up. How long will this re-re-evaluation likely take?

Sorry, I guess my frustration is showing a bit here. Glad to talk by phone if that would help. 301-641-0104

Francis

From Chris Austin:

ACTIV-1: Janet is not comfortable with the protocol as is, given the RECOVERY dex data (see <https://www.medrxiv.org/content/10.1101/2020.06.22.20137273v1> just out), the many other immunomodulators she knows are being tested by companies, and objections she heard DAIT had. She wants to see the original evaluation that ACTIV did to select the three compounds, and the written comments from DAIT. She thinks the protocol will likely need to be re-written to account for dex; she brought up again the concept of the "screening trial." To decide what to do, she wants a meeting with her extended group and NCATS

From: Woodcock, Janet { b6 }
Sent: Thursday, June 18, 2020 4:41 PM
To: Collins, Francis (NIH/OD) [E] { b6 }
Subject: got \$\$ for immunomodulator study

But they are not ready yet. Will provide when they are ready. jw

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 6/26/2020 11:52:44 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: got \$\$ for immunomodulator study

It was requested several times on the call we had with her yesterday, and decided on as the action item from the call.

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, June 25, 2020 10:37 PM
To: Austin, Christopher (NIH/NCATS) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: got \$\$ for immunomodulator study

Chris,
I do not see a call specifically requested in Janet's note, and I think an all-hands call is not likely to be productive.

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Thursday, June 25, 2020 8:09 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: got \$\$ for immunomodulator study

Will do, let me know if anyone wants additional people on the call Janet requested in addition to those I listed. I will get this scheduled tomorrow.

Sent from my iPhone

On Jun 25, 2020, at 7:49 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Glad to see she doesn't seem to be inclined to re-litigate the case for the three specific immunomodulators. If it's just about dexamethasone and SOC, let's do this! And quickly!

Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, June 25, 2020 7:48 PM
To: Woodcock, Janet [b6]
Subject: RE: got \$\$ for immunomodulator study

Thanks, Janet, that's reassuring, let's move ahead quickly and get this resolved.

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To: Woodcock, Janet [b6]
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Sorry, I guess my frustration is showing a bit here. Glad to talk by phone if that would help. [REDACTED] b6

Francis

From Chris Austin:

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From: Woodcock, Janet [REDACTED] b6
Sent: Thursday, June 18, 2020 4:41 PM
To: Collins, Francis (NIH/OD) (E) [REDACTED] b6
Subject: got \$\$ for immunomodulator study

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From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 6/26/2020 11:51:10 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: got \$\$ for immunomodulator study

Ok sounds good. She's very open to discussion, just wants to do the right thing medically given the changes in the therapeutic landscape for COVID.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, June 26, 2020 5:29 AM
To: Austin, Christopher (NIH/NCATS) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: got \$\$ for immunomodulator study

Hi Chris,

Before you set up this larger discussion, it may be advantageous for David and Stacey to have a conversation with Janet. She may not be aware of what the Therapeutics WG has already done about these issues. Let's discuss at War Room today.

FC

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Thursday, June 25, 2020 8:09 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: got \$\$ for immunomodulator study

Will do, let me know if anyone wants additional people on the call Janet requested in addition to those I listed. I will get this scheduled tomorrow.

Sent from my iPhone

On Jun 25, 2020, at 7:49 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Glad to see she doesn't seem to be inclined to re-litigate the case for the three specific immunomodulators. If it's just about dexamethasone and SOC, let's do this! And quickly!

Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, June 25, 2020 7:48 PM
To: Woodcock, Janet [b6]
Subject: RE: got \$\$ for immunomodulator study

Thanks, Janet, that's reassuring, let's move ahead quickly and get this resolved.

Best, Francis

From: Woodcock, Janet [b6]
Sent: Thursday, June 25, 2020 6:58 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: got \$\$ for immunomodulator study

Well I think it is pretty straightforward. The funding is available. The landscape has changed though. The therapeutics working group did not have the advantage of the full description of the RECOVERY dexamethasone arm. It looks pretty solid to me. Neither the funders of the trial nor the sponsors of the trial can move forward until we are sure the design conforms to ethical principles. No matter what other groups have said, we (NCATS and OWS) will be responsible for this. So we have to take a close look at the RECOVERY results and decide if it is still ethical to randomize to a SOC that does not include dexamethasone, and if it does, how do we add immunomodulators? We can do this quickly and the money is available, but it must be done. NCAT might move forward with selecting a CRO while we work this out. jw

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, June 25, 2020 6:22 PM
To: Woodcock, Janet [b6]
Subject: RE: got \$\$ for immunomodulator study

Hi Janet,

I just got a message from Chris Austin (his summary is below, please tell me if this is not accurate). Now I am really confused about ACTIV-1 (the three immunomodulators). When Moncef was skeptical about the scientific basis for the choice of these three agents (on May 29, almost four weeks ago), we went through that in considerable detail, and he eventually agreed (or at least didn't object). You sent me a note a week ago (below) saying that the \$\$ had been allocated. So we moved ahead.

But now? I was disappointed that DAIT was not enthusiastic about the trial, but they are traditionally a rather academic group and didn't like the idea of having to do things this quickly and take risks that it might now work. So we moved quickly to identify a CRO model through NCATS and Duke, and that looked like the right way to get this done. ACTIV-1 has already taken

longer to launch this than it should, so we were highly motivated to get it going. The Therapeutics WG already looked at the protocol, and my understanding is that the dex study did not change their view on how the study should be conducted (though I don't have the details on this).

I fear the companies are going to walk pretty soon if this doesn't get underway. The ACTIV Therapeutics WG will be deeply demoralized if this all blows up. How long will this re-re-evaluation likely take?

Sorry, I guess my frustration is showing a bit here. Glad to talk by phone if that would help. [REDACTED] b6

Francis

From Chris Austin:

ACTIV-1: Janet is not comfortable with the protocol as is, given the RECOVERY dex data (see <https://www.medrxiv.org/content/10.1101/2020.06.22.20137273v1> just out), the many other immunomodulators she knows are being tested by companies, and objections she heard DAIT had. She wants to see the original evaluation that ACTIV did to select the three compounds, and the written comments from DAIT. She thinks the protocol will likely need to be re-written to account for dex; she brought up again the concept of the "screening trial." To decide what to do, she wants a meeting with her extended group and NCATS

From: Woodcock, Janet [REDACTED] b6
Sent: Thursday, June 18, 2020 4:41 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Subject: got \$\$ for immunomodulator study

But they are not ready yet. Will provide when they are ready. jw

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 6/18/2020 8:33:29 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: FW: Materials for todays OWS Meeting at 5pm
Attachments: 06 18 20 OWS Board Agenda v.3 docx; 18Jun2020_OWS_Board_Rx_deck_Final.pptx

Check this out. More info here on mAbs.

Close hold, not for distribution.

FC

From: Tignor, Beth (HHS/IOS) [b6]
Sent: Thursday, June 18, 2020 2:06 PM
To: Tignor, Beth (HHS/IOS) [b6]; Apple, Matthew (HHS/IOS) [b6]
Subject: Materials for todays OWS Meeting at 5pm

Good afternoon All,
Please find attached Materials for today's meeting. We will provide printed materials for those attending in person. See you all soon.

Beth Tignor
Director of Scheduling
The Department of Health and Human Services

b6

Confidential and pre-decisional communication



18] un2020_OW...



06 18 20 OWS
Board Agenda v....

APAR0000005019

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 6/16/2020 3:18:31 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: Factsheet: Explaining Operation Warp Speed

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, June 16, 2020 10:51 AM
To: Collins, Francis (NIH/OD) [E] [b6]; NIH Director's Executive Committee <OD-SmallStaff@mail.nih.gov>
Cc: Prince, Scott (NIH/OD) [E] [b6]; OCPLPressTeam <OCPLPressTeam@od.nih.gov>; Kolberg, Rebecca (NIH/OD) [E] [b6]; Pelis, Kim (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]; Kuska, Bob (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Factsheet: Explaining Operation Warp Speed



U.S. Department of Health and Human Services

News Release

202-690-6343
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www.hhs.gov/news
Twitter [@SpoxHHS](https://twitter.com/SpoxHHS)

FOR IMMEDIATE RELEASE
Tuesday, June 16, 2020

Factsheet: Explaining Operation Warp Speed

What's the goal?

APAR0000005023

Operation Warp Speed (OWS) aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures).

How will the goal be accomplished?

By investing in and coordinating countermeasure development, OWS will allow countermeasures such as a vaccine to be delivered to patients more rapidly while adhering to standards for safety and efficacy.

Who's working on it?

OWS is a partnership among components of the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD). OWS engages with private firms and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. It will coordinate existing HHS-wide efforts, including the NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, NIH's Rapid Acceleration of Diagnostics (RADx) initiative, and work by BARDA.

What's the plan and what's happened so far?

Development: To accelerate development while maintaining standards for safety and efficacy, OWS has been selecting the most promising countermeasure candidates and providing coordinated government support.

Protocols for the demonstration of safety and efficacy are being aligned, which will allow the trials to proceed more quickly, and the protocols for the trials will be overseen by the federal government, as opposed to traditional public-private partnerships, in which pharmaceutical companies decide on their own protocols. Rather than eliminating steps from traditional development timelines, steps will proceed simultaneously, such as starting manufacturing of the vaccine at industrial scale well before the demonstration of vaccine efficacy and safety as happens normally. This increases the financial risk, but not the product risk.

Select actions to support OWS vaccine development so far include:

- March 30: HHS announced \$456 million in funds for Johnson & Johnson's candidate vaccine, with Phase 1 clinical trials set to begin this summer.
- April 16: HHS made up to \$483 million in support available for Moderna's candidate vaccine, which began Phase 1 trials on March 16 and received a fast-track designation from FDA.
- May 21: HHS announced up to \$1.2 billion in support for AstraZeneca's candidate vaccine, developed in conjunction with the University of Oxford. The agreement is to make available at least 300 million doses of the vaccine for the United States, with the first doses delivered as early as October 2020 and Phase 3 clinical studies beginning this summer with approximately 30,000 volunteers in the United States.

As announced on May 15, the vaccine development plan is as follows, subject to change as work proceeds:

- Fourteen promising candidates have been chosen from the 100+ vaccine candidates currently in development—some of them already in clinical trials with U.S. government support.

- The 14 vaccine candidates are being narrowed down to about seven candidates, representing the most promising candidates from a range of technology options, which will go through further testing in early-stage clinical trials.
- Large-scale randomized trials for the demonstration of safety and efficacy will proceed for the most promising candidates.

Manufacturing: The federal government is making investments in the necessary manufacturing capacity at its own risk, giving firms confidence that they can invest aggressively in development and allowing faster distribution of an eventual vaccine. Manufacturing capacity for selected candidates will be advanced while they are still in development, rather than scaled up after approval or authorization. Manufacturing capacity developed will be used for whatever vaccine is eventually successful, if possible given the nature of the successful product, regardless of which firms have developed the capacity.

Select actions to support OWS manufacturing efforts so far include:

- The May 21, April 16, and March 30 HHS agreements with AstraZeneca, Moderna, and Johnson & Johnson respectively include investments in manufacturing capabilities.
- June 1: HHS announced a task order with Emergent BioSolutions to advance domestic manufacturing capabilities and capacity for a potential COVID-19 vaccine as well as therapeutics, worth approximately \$628 million.

Distribution: Before the countermeasures are approved or authorized, the program will build the necessary plans and infrastructure for distribution.

HHS plans for a tiered approach to vaccine distribution, which will build on allocation methodology developed as part of pandemic flu planning and be adjusted based on experience during the first wave of the COVID-19 response, data on the virus and its impact on populations and the performance of each vaccine, and the needs of the essential workforce. OWS will expand domestic manufacturing and supplies of specialized materials and resources, such as glass vials, that can be necessary for distribution. DoD's involvement will enable faster distribution and administration than would have otherwise been possible.

Select actions to support OWS distribution efforts include:

- May 12: DoD and HHS announced a \$138 million contract with Apiject for more than 100 million prefilled syringes for distribution across the United States by year-end 2020, as well as the development of manufacturing capacity for the ultimate production goal of over 500 million prefilled syringes in 2021.
- June 9: HHS and DoD announced a joint effort to increase domestic manufacturing capacity for vials that may be needed for vaccines and treatments:
 - \$204 million to Corning to expand the domestic manufacturing capacity to produce an additional 164 million Valor Glass vials each year if needed.
 - \$143 million to SiO2 Materials Science to ramp up capacity to produce the company's glass-coated plastic container, which can be used for drugs and vaccines.

Who's leading OWS?

HHS Secretary Alex Azar and Defense Secretary Mark Esper oversee OWS, with Dr. Moncef Slaoui designated as chief advisor and General Gustave F. Perna nominated to be chief operating officer. To allow these OWS leaders to focus on operational work, in the near future the program will be announcing separate points of contact, with deep expertise and involvement in the program, for communication with Congress and the public.

What are you doing to make these products affordable for Americans?

As a commitment to making countermeasures affordable for the American people, and as a condition of receiving support from OWS, companies will provide to the U.S. government an allocation of countermeasures developed.

How is this being funded?

Congress has directed almost \$10 billion to this effort through supplemental funding, including the CARES Act. Congress has also appropriated other flexible funding. The almost \$10 billion specifically directed includes more than \$6.5 billion designated for countermeasure development through BARDA and \$3 billion for NIH research.

To view a PDF of this fact sheet, please visit [here](#).

###

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From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 6/11/2020 11:58:12 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: Following up

Double yay!!!! Quiet as moths worked, she says with a smile. Great job Francis! M.

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Thursday, June 11, 2020 at 7:56:16 AM
To: "Freire, Maria (FNIH) [T]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: Following up

Yay!

From: Woodcock, Janet [b6]
Sent: Thursday, June 11, 2020 7:49 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: Following up

It is resolved, we will get you the funds, I just haven't gotten the money from OMB. Presented to them yesterday. You might check with the dept. budget people on how it is going, they are working on it. jw

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, June 10, 2020 9:14 PM
To: Woodcock, Janet [b6]
Subject: RE: Following up

Hi Janet,

Just checking in again to see where things stand with the immunomodulator trial. Everyone is champing at the bit to get started. Anything I need to do to help get this resolved?

Francis

From: Woodcock, Janet { b6 }
Sent: Monday, June 8, 2020 8:19 PM
To: Collins, Francis (NIH/OD) [E] { b6 }
Subject: Re: Following up

Thanks. I'll talk to him tomorrow if that is ok. I think this trial will be a go. I still have to present to OMB so am a bit unclear on when the \$\$ will flow. Jw

From: Collins, Francis (NIH/OD) [E] { b6 }
Date: June 8, 2020 at 7:54:42 PM EDT
To: Woodcock, Janet { b6 }
Subject: FW: Following up

Hey there Janet,

I'm thinking we should get a response back to Moncef about these last questions on the three immunomodulators proposed for the ACTIV-1 trial, since he promised the OWS Board he would have a decision by this coming Friday. The protocol is 98% done, and NIAID has agreed to take on the role of coordinating the trial, probably with help from a CRO. Following Debbie Bix's question, the ACTIV Therapeutic Prioritization Subgroup has looked carefully at the items listed on p. 22 of last Thursday's handout, and reported they were fully aware of the projects listed in the BARDA column, and did not conclude that any of those would belong on the ACTIV-1 short list. In the DoD column, the one drug that was potentially of interest was favipiravir, but you were going to look into that.

Meanwhile, I know Justin Hentges was digging up other NIH funding spent on COVID-19 therapeutics that are not part of OWS, and I think that went to you today.

How can I help with this response to Moncef? I'm glad to do whatever I can.

Best, Francis

From: Slaoui, Moncef { b6 }
Sent: Friday, June 5, 2020 3:36 AM
To: Collins, Francis (NIH/OD) [E] { b6 }
Cc: moncef slaoui { b6 }; Woodcock, Janet (FDA/CDER) { b6 }; Wholley, David (FNIH) [T] { b6 }
Subject: Re: Following up

Hi Francis

Thank you for following up

I really only wanted to discuss how the funding may work as there is a chance the trial may not complete Fully for each in the medicines, either because it is stopped by the DSMB for futility and/ or because one of the smaller trials with Abatacept in Europe for instance may yield an outcome not supporting progressing ...

Janet how do you intend to oversee the "immuno-inflammation" and the "anti coagulation" trials?

Once these points are clarified and we have clarified the question Dr Bix was insisting on, then we are good to go. Maybe you can send something re the programs BARDA and DARPA have ongoing that haven't selected By ACTIV? Janet states that there are more than those listed on the appendix

I will review the ACTIV leadership group deck over the week end and get back to you

With my best regards

Moncef

Tel: [b6]

On Jun 4, 2020, at 11:14 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi Moncef,

That was an excellent presentation at OWS – you and Janet have done a tremendous amount of work to pull this all together.

I note that you indicated to the Board a plan to make a decision about the immunomodulators by next Friday. I stand ready to provide any other information that might help with this. The protocol (ACTIV-1) is 90% done, and the JnJ folks are lobbying hard to get started on infliximab. The ACTIV therapeutics-clinical WG continues to have strong support for cenicriviroc and abatacept, and I frankly worry that this group of public and private experts will be quite disheartened if their hard work and thoughtful analysis is overruled. Would you want to talk to the co-chairs directly? Janet and I will check out the projects that Debbie Birx pointed to on p. 22, but I very much doubt if any of these are in a position to be adopted by ACTIV-1.

I also thought you might be interested in the slide deck from the ACTIV Leadership Group meeting from yesterday, so I have attached that. It was an excellent meeting with a lot of engagement and vigorous discussion from the ~65 participants. I'd be glad to answer questions about any parts of this. In fact, if you had time, David Wholley and I would welcome the chance to walk you through the materials. Just let me know.

Best, Francis

<ACTIV Leadership Team Meeting 20200603 FINAL.pptx>

From: Woodcock, Janet [b6]
Sent: 6/5/2020 5:27:06 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: RE: 04JUN2020_OWS Board Meeting_slide 22 only.pptx

I'll ask our DOD contact about the status of the favipiravir study, I was wondering about that myself. jw

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, June 5, 2020 12:04 PM
To: Wholley, David N (NIH) [b8]; Woodcock, Janet [b6]
Cc: Tabak, Lawrence A (NIH) [b6]; Adam, Stacey J (NIH) [b6]; Freire, Maria C (NIH) [b6]; Lane, Henry C (NIH) [b6]; Lane, Henry C (NIH) [b6]; Austin, Christopher P (NIH) [b8]; Parker, Ashley S (NIH) [b6]; Anderson, James M (NIH) [b8]
Subject: RE: 04JUN2020_OWS Board Meeting_slide 22 only.pptx

Thanks, David, this is very helpful.

I'm looping in Janet, as I know she was interested in the answer to Dr. Birx's question. Janet, I'm glad to work with you in figuring out how best to convey this information to Dr. Birx.

Francis

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, June 5, 2020 11:28 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: FW: 04JUN2020_OWS Board Meeting_slide 22 only.pptx

Hi Francis,

Thank you for sending the slide from the OWS Board Meeting yesterday listing the agents that BARDA and DoD had begun testing prior to the advent of OWS. In response to the inquiry regarding these from the OWS Board Meeting yesterday I have checked with our staff and can report that the ACTIV Therapeutics-Clinical working group and its drug prioritization team were in fact aware of the agents BARDA had agreed to test. In fact ACTIV included personnel from BARDA on our agent prioritization team who let the team know about the classes of agents they were testing and at the proposed level/phase of testing. The prioritization group deliberately avoided duplicating the BARDA funded efforts (IL-6 and IL-22) and also steered clear of convalescent plasma because of awareness that these were already being adequately tested by BARDA and others.

As you know, DoD was involved a bit later in the ACTIV process than BARDA, and the ACTIV group had not seen the DoD testing efforts listed on this slide. One of the antivirals that DoD is studying, favipiravir, is in fact currently on the ACTIV prioritization group's list of agents to consider; however it was not picked in the first wave of prioritization and can be excluded from the second wave if DoD is moving forward with their plans for testing. It would be good to get the name of a contact familiar with that project so we make sure the consideration is done formally and carefully.

There are also a number of companies on the BARDA and DoD lists that have neutralizing mAbs and who are also on the list of companies invited to the mAb Summit that ACTIV is co-hosting with OWS on June 9. If I read this slide correctly, however, it looks like most of what DoD and BARDA are funding are Phase 1, early Phase 2, and manufacturing, so the planned ACTIV mAb trials and testing efforts should complement DoD's and BARDA's efforts to date well.

Please let me know if you need more information this subject, or if there are other recommendations regarding ACTIV's agent prioritization process.

David Wholley

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 6/5/2020 3:31:21 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: RE: 04JUN2020_OWS Board Meeting_slide 22 only.pptx

Very helpful. Thanks David, M.

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, June 5, 2020 11:28 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
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Please let me know if you need more information this subject, or if there are other recommendations regarding ACTIV's agent prioritization process.

David Wholley

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 6/5/2020 12:15:30 AM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: Re: Quick summary of OWS

Francis,
I agree with Maria; the cup is half-full. You have made significant progress from where this all started.
Thanks
Larry

From: "Freire, Maria (FNIH) [T]" [b6]
Date: Thursday, June 4, 2020 at 7:52 PM
To: Francis Collins [b6]; "Wholley, David (FNIH) [T]" [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]; "Lane, Cliff (NIH/NIAID) [E]" [b6]; "Austin, Christopher (NIH/NCATS) [E]" [b6]; "Parker, Ashley (NIH/OD) [E]" [b6]; "Anderson, James (NIH/OD) [E]" [b6]
Subject: Re: Quick summary of OWS

Francis, all in all this was a really solid outcome. We still have work on the immunomodulators but Moncef had enough info to speak to them. which is very good. Your point 7 gives me hope!

Don't know what to tell you about Birx.

And tomorrow is another day.

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Thursday, June 4, 2020 at 7:36:20 PM
To: "Wholley, David (FNIH) [T]" [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]; "Lane, Cliff (NIH/NIAID) [E]" [b6]; "Freire, Maria (FNIH) [T]" [b6]; "Austin, Christopher (NIH/NCATS) [E]" [b6]; "Parker, Ashley (NIH/OD) [E]" [b6]; "Anderson, James (NIH/OD) [E]" [b6]
Subject: Quick summary of OWS

Hi all,

The OWS presentation by Moncef and Janet mostly went well, but with a few heartburn moments. Debbie Birx pretty much ran the meeting – Azar was calling from an airport, Kushner and Esper were no shows.

Regular mention by Moncef and Janet of help from NIH and ACTIV. Birx, on the other hand, seems to think that ACTIV is just NIH, and I had to correct her on that. Points that came up that wouldn't be obvious from the ppts:

1. mAb cocktails – Moncef clearly thinks those are superior to single agents. Janet less convinced, but raised the possibility of in vitro testing to find ideal combinations, which everyone loved. Birx insisted that neutralization assays (NA) on all mAbs should be done in more than one independent laboratory, and should be blinded. Based on Cliff's response earlier today, I said I thought that USAMRIID/Ft. Dietrick was a good candidate to help with both individual mAb NAs and combinations.
2. Birx was very worried about running mAb trials in July-August and whether the patients would still be there. I was tempted to crow about the ACTIV geomapping tool, but held back.
3. Everyone seems upset with Mayo for not having delivered the data on Ab titers for the convalescent plasma yet, and the June 15 deadline might slip to June 30.
4. Anticoagulants breezed through without much comment – including the outpatient part, which may not have been noted in footnote 6 of slide 8.
5. Immunomodulators are, sadly, not yet a done deal. Moncef tried to say this decision would be made next week, but Birx demanded to know the status. So he went through the three compounds. He clearly endorsed infliximab, citing the RA and IBD data. Said the other two needed more discussion.
6. Here's where it got a little weird. Birx wanted everyone to turn to pp. 22 in the handout. That lists government investments from BARDA and DOD prior to arrival of OWS. Birx wanted to know whether ACTIV had considered the immune modulators and antivirals in their priority setting. Janet tried to explain that these are trials that are already underway and didn't need help from ACTIV, but Birx didn't seem to buy that. To move things along, I said we would check if these were considered in the therapeutics priority setting. Janet said she would help sort this out. Seems like a big distraction, but we'll need to respond.
7. Therapeutics discussion ended with slide 8, which was generally well received. Yep, that's \$5.6B for therapeutics.
8. Then Matt Hepburn went into the vaccine slide deck (it now being well past an hour). High points were complaints that Moderna is trying to negotiate too high a price (\$30), Pfizer is being aggressive about demanding to use NIAID sites (Moncef sounded quite incensed about this, and agrees that you can't have the same site running two different vaccine trials unless they are part of the same randomized protocol), and major unhappiness from Birx that AZ has still not produced the data from their Phase I/II trial – though the UK IRB must have seen it to approve the phase III UK trial, which just started. AZ has also obtained approval to run a trial in Brazil – so they must have seen the data also.

That's it from here.

Francis

From: Fauci, Anthony (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DF38103D75134F658AE2D356F0396B94-AFAUCI]
Sent: 6/5/2020 10:50:34 AM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Following up

Indeed. Moncef in hanging in there with us.

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Friday, June 5, 2020 5:45 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Following up

Francis,
You are clearly reaching him. This looks like it will have a very favorable end result.
Thanks
Larry

From: Francis Collins [b6]
Date: Friday, June 5, 2020 at 5:35 AM
To: Anthony Fauci [b6], "Freire, Maria (FNIH) [T]" [b6], "Wholley, David (FNIH) [T]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: Following up

This sounds pretty encouraging.

From: Slaoui, Moncef [b6]
Sent: Friday, June 5, 2020 3:36 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: moncef slaoui [b6]; Woodcock, Janet (FDA/CDER) [b6]

Wholley, David (FNIH) [T] [b6]

Subject: Re: Following up

Hi Francis

Thank you for following up

I really only wanted to discuss how the funding may work as there is a chance the trial may not complete Fully for each in the medicines, either because it is stopped by the DSMB for futility and/ or because one of the smaller trials with Abatacept in Europe for instance may yield an outcome not supporting progressing ...

Janet how do you intend to oversee the "immuno-inflammation" and the " anti coagulation" trials?

Once these points are clarified and we have clarified the question Dr Birx was insisting on, then we are good to go.

Maybe you can send something re the programs BARDA and DARPA have ongoing that haven't selected By

ACTIV? Janet states that there are more then those listed on the appendix

I will review the ACTIV leadership group deck over the week end and get back to you

With my best regards

Moncef

Tel: 202 834 0588

On Jun 4, 2020, at 11:14 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi Moncef,

That was an excellent presentation at OWS – you and Janet have done a tremendous amount of work to pull this all together.

I note that you indicated to the Board a plan to make a decision about the immunomodulators by next Friday. I stand ready to provide any other information that might help with this. The protocol (ACTIV-1) is 90% done, and the JnJ folks are lobbying hard to get started on infliximab. The ACTIV therapeutics-clinical WG continues to have strong support for cenicriviroc and abatacept, and I frankly worry that this group of public and private experts will be quite disheartened if their hard work and thoughtful analysis is overruled. Would you want to talk to the co-chairs directly? Janet and I will check out the projects that Debbie Birx pointed to on p. 22, but I very much doubt if any of these are in a position to be adopted by ACTIV-1.

I also thought you might be interested in the slide deck from the ACTIV Leadership Group meeting from yesterday, so I have attached that. It was an excellent meeting with a lot of engagement and vigorous discussion from the ~65 participants. I'd be glad to answer questions about any parts of this. In fact, if you had time, David Wholley and I would welcome the chance to walk you through the materials. Just let me know.

Best, Francis

<ACTIV Leadership Team Meeting 20200603 FINAL.pptx>

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 6/3/2020 1:38:42 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: ACTIV immunomodulators -- responses to request for further information
Attachments: ACTIV Therapeutics Prioritization_060220.docx

Hi all,

Many thanks to David and Stacey for providing this 19 pp document that summarizes the ACTIV process for prioritizing therapeutics, leading to the selection of the three immunomodulators that we now wish to study in ACTIV-1. I made a few mostly cosmetic edits in the very nice document, and then sent it on to Moncef. I mentioned this to him this afternoon in the White House, and he said he was looking forward to seeing it tonight.

Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, June 2, 2020 9:35 PM
To: moncef slaoui [b6]
Cc: Woodcock, Janet (FDA/CDER) [b6]; Wholley, David (FNIH) [T] [b6]
Adam, Stacey (FNIH) [T] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Subject: ACTIV immunomodulators -- responses to request for further information

Hi Moncef,

Following up our discussion last Saturday, I asked David Wholley and Stacey Adam of the Foundation for NIH (who serve as highly capable ACTIV program managers) to put together more detailed information about how the ACTIV therapeutic prioritization process has functioned. The attached document outlines that process in a series of ten steps. This prioritization process has been conducted by members of the ACTIV Clinical Therapeutics Working Group, co-chaired by Eric Hughes (Novartis) and Sarah Read (NIAID).

The document also provides additional background on the three therapeutic agents that were assigned the highest priority. The company producing each of these has indicated enthusiasm for participation, and assured ACTIV leadership that there would not be a problem in scaling up production, should a trial prove positive.

The ACTIV team and its Executive Committee endorsed the immediate testing of these three immunomodulators for hospitalized COVID-19 patients. The urgency of the effort to save lives of the sickest COVID-19 patients was considered

sufficient reason to go directly to a Phase III trial (but with aggressive stopping rules for safety and futility), rather than a more traditional Phase II approach. As we discussed last Saturday, therefore, we seek approval to initiate the trial as soon as possible, at an estimated cost of \$70M.

Please let me, David, and Stacey know if you need additional information.

Best regards, Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 12/17/2020 8:53:31 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: OWS Board meeting -- confidential
Attachments: 2020-12-18 OWS board briefing Vx Tx overview Final.pdf

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 9/8/2020 4:55:15 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Automatic reply: DRAFT NIH and ACTIV Clinical Trial Grid

I am currently out of the office on annual leave. For September 8-9, I will only work a half day and may not be checking and answering emails as quickly as usual. For September 10-12, I will not be working and will only be answering emails intermittently.

If you need something in regards to ACTIV Therapeutics-Clinical WG, please email Mike Santos [b6] and Helen Chen (qingchen@deloitte.com). They will be able to direct you to the correct individuals for either Agent Prioritization or any of the ACTIV master protocols. If it is not urgent, I will reply to you as I can.

If a matter is very urgent and needs my specific attention, please text my cell phone [b6] and I will return your message as soon as I can.

If you need something for ACT4PEDS (Preclinical Pediatric Oncology PPP), please email Tanya Murza [b6].

If you need something for PACT, please email Jenny Peterson-Klaus [b6].

If you need something for Lung-MAP, please email Amrin Chowdhury [b6].

If you need something for the Biomarkers Consortium CSC, please email Dana Connors [b6].

Thank you,

Stacey

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 9/9/2020 3:41:56 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]
Subject: FW: DRAFT NIH and ACTIV Clinical Trial Grid
Attachments: DRAFT ACTIV Checkerboard_9.4.20.pptx

Hi Ashley and David,

Can we present this to our TX-Clinical WG team members ahead of our meeting tomorrow, so we can ensure a productive feedback discussion of what they think is missing?
Or can this not be sent around broadly yet?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6] >
Sent: Tuesday, September 8, 2020 12:54 PM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: DRAFT NIH and ACTIV Clinical Trial Grid

Good afternoon,

I hope everyone had a great holiday. I know there was interest from the Tx clinical WG to review the NIH and ACTIV clinical trial grid. Attached is a version that does not display agents/trial information that has not yet launched but has a placeholder for those trials "coming soon."

Please note this is still a working draft as we continue to add trials as they launch (agents for ACTIV-4 inpatient trial will be included once the trial launches this week).

We standby for any major edits the WG may have.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/1/2020 9:03:59 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: Talking points for tomorrow morning's ACTIV-3 investigator call

Francis:

Here are the key themes for your meeting with the ACTIV-3 site investigators. They were agreed between Stacey Adam and Libby Higgs of NIAID:

- NIH, ACTIV, and OWS leadership are very supportive of the trial and the sites conducting it and want to ensure proper resources for trial conduct
- We understand there are challenges being faced to recruitment in the current pandemic
- Sites should think about how ACTIV could help them to ensure smooth stand up of the ACTIV-3 trial
- Importance of prioritizing ACTIV trials (trials are powered for results, benefit from careful design by many experts, carefully prioritized agents etc.)

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 9/2/2020 2:56:33 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: [EXTERNAL] RE: Regeneron and ACTIV 3

Regeneron will give us lots of headaches, but the value of adding them to ACTIV-3 will probably make it worth it.

FC

From: Wholley, David (FNIH) [T] <[REDACTED] b6 >
Sent: Wednesday, September 2, 2020 9:43 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >
Cc: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6 >; Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Subject: FW: [EXTERNAL] RE: Regeneron and ACTIV 3

Fyi, still preliminary.

From: Harrigan, Rachel (HHS/IOS) <[REDACTED] b6 >
Sent: Tuesday, September 1, 2020 7:54 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED] b6 >; Woodcock, Janet (FDA/CDER) <[REDACTED] b6 >
Wholley, David (FNIH) [T] <[REDACTED] b6 >; Lane, Cliff (NIH/NIAID) [E] <[REDACTED] b6 >; Bugin, Kevin (FDA/CDER) <[REDACTED] b6 >
Subject: RE: [EXTERNAL] RE: Regeneron and ACTIV 3

Hi Janet,

I agree with Stacey, I think the team would be very interested in pursuing this.

Suggest consider adding Libby Higgs to the invite list – I'd wager she would have useful expert input on the virology information, besides general clinical considerations.

Best
Rachel

From: Adam, Stacey (FNIH) [T] <[REDACTED] b6 >
Sent: Tuesday, September 1, 2020 7:47 PM
To: Woodcock, Janet (FDA/CDER) <[REDACTED] b6 >; Wholley, David (FNIH) [T] <[REDACTED] b6 >
Lane, Cliff (NIH/NIAID) [E] <[REDACTED] b6 >; Bugin, Kevin (FDA/CDER) <[REDACTED] b6 >
Cc: Harrigan, Rachel (HHS/IOS) <[REDACTED] b6 >
Subject: [EXTERNAL] RE: Regeneron and ACTIV 3

CAUTION: This message was sent from an external source. Please do not click links or open attachments unless you recognize the source of this email and are sure the content is safe.

APAR0000005066

Hi Janet,

I can't speak for the rest of the team, but think the ACTIV-3 team would be interested in this given this agent will likely be ready ahead of some of the others, but we should likely at least ask Jens and Jim. Rachel would you concur?

Also, a question, would this take one of the OWS sponsored Phase 3 slots?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Woodcock, Janet [b6]
Sent: Tuesday, September 1, 2020 7:39 PM
To: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Bugin, Kevin (FDA/CDER) [b6]
Cc: Harrigan, Rachel (HHS/IOS) [b6]
Subject: Regeneron and ACTIV 3

Regeneron told me that they'd like to come into ACTIV 3 part 2 but they would like a small group of people to talk to them and walk them thru the process. They have enrolled a lot of people (blinded) but have not had any SAEs. Their OP trial is enrolling well but their inpatient trial is not. They are willing to share the blinded data but not unblind the ongoing study. They would go with their highest dose. They are willing to share their (blinded) virology data which sounds very interesting to me. If there is still interest in this at NIH/FNIH I thought that a group including me, Stacy, Cliff, the NIH lead and a study PI could talk to them. I told George Y that they would have to go through a vetting process and submit some data on their Ab and experience so far. This seemed OK to him but he asked for this conversation first.

Are people interested/ willing? jw

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/3/2020 9:56:24 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: Letter discussed
Attachments: ACTIV_TX-Clinical_Master Protocol_ACTIV-3 Site Investigators Meeting_20200902.docx

Hi Francis (copying war room as well):

Thank you again for your very effective presentations at the meetings with the ACTIV-3 and ACTIV-2 investigators yesterday and today. As one of the investigators on today's ACTIV-2 call said, hearing from you "should make us all feel personally privileged to be a part of something so important."

Attached are the meeting notes from the ACTIV-3 Investigators call yesterday along with some ideas generated in a further meeting with the ACTIV-3 team today, which are noted below. The meeting notes include the key action items discussed so far—most involving requests for follow-up from you and/or Janet. I thought you should see all these in advance of tomorrow morning's war room.

The notes and action items from today's ACTIV-2 Investigator call should be available soon. The specific ACTIV-2 action items I heard were:

- 1) Work with local government agencies to refer people to the trial(s).
- 2) Step up social media presence.
- 3) Include the ACTIV trials in the links available on the coronavirus.gov website. Currently this website only links to the CoVPN trial.

We have also made progress on the formal "needs assessment" survey of ACTIV-2 and -3 we have been discussing this week; I will update the group on that tomorrow morning.

Thanks, David

From: Higgs, Elizabeth (NIH/NIAID) [E] [b6]
Sent: Thursday, September 3, 2020 2:43 PM
To: Adam, Stacey (FNIH) [T] [b6]; McNay, Laura (NIH/NIAID) [E] [b6]

Cc: Harrigan, Rachel (HHS/IOS)

b6

Subject: Re: Letter discussed

Stacey,

Additional feedback from this meeting. Laura and Rachel, please add in.

There was general consensus that we need a media campaign targeting Universities, physicians, not so much patient populations as in Klick that we reviewed for ACTIV 2 in the TOC meeting. We were thinking this could include:

- 1) General letter from Dr. Collins and or ICs to their Extramural NIH grant recipients about ACTIV 3, the priority of the study, the need for supporting, enrolling quickly, etc.
- 2) Perhaps op ed letter from Dr. Collins, Fauci, Woodcock in the NY times or elsewhere.
- 3) Maybe use social media, e.g. Dr. Collins Directors blog
- 4) Media spot light on ACTIV 3 etc.

I would think the ACTIV EC and OWS would need to agree/approve.

Thanks,
Libby

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 8/31/2020 8:24:09 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: FYI: FW: Discussion about Short Site Survey to Determine COVID Trial Burden

Thanks!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 4:20 PM
To: Culp, Michelle (NIH/OD) [E] [b6]
Subject: Re: FYI: FW: Discussion about Short Site Survey to Determine COVID Trial Burden

Done!

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Aug 31, 2020, at 4:17 PM, Culp, Michelle (NIH/OD) [E] [b6] wrote:

Ashley,
Thanks for filling me in. Do you have a copy of the letter, and if so, can you share it with me? If not, I'll ask FNIH about it.

-Michelle

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 4:08 PM
To: Culp, Michelle (NIH/OD) [E] [b6]
Subject: Re: FYI: FW: Discussion about Short Site Survey to Determine COVID Trial Burden

Hi Michelle,

The IRB letters were signed and sent out last week to my understanding.

Best,
Ashley

On Aug 31, 2020, at 3:46 PM, Culp, Michelle (NIH/OD) [E] [b6] wrote:

Dear Carrie,
I'm just returning from a couple days of leave and being unplugged. In catching up, I saw these notes on ideas for ACTIV 2 & 3 recruitment solutions, and mention of the **central IRB letter**.

Item #10 in the attached notes from David Wholley (section pasted below) mentions the central IRB letter as a good model. The notes made me wonder if the IRB letter was

distributed, and if not, is FNIH and study teams are aware of the final messaging in the IRB letter.

10. A few additional notes/caveats on such a public campaign: It should ideally have a global component, since COVID-19 is a global pandemic and a good number of our sites are outside the U.S. Although we might be able to use the ACTIV protocols as an example of the kind of studies in which people should participate (as opposed to small, underpowered studies that are the norm), we need to be very careful that this is a general exhortation to participate in COVID-19 trials, and not appear to be exclusionary, or we will hear vocal objections to say the least from other trial sponsors. Also, the central IRB letter authored by Francis Collins and a related letter sent to the study PIs offers a good model. Finally, any such communication needs both a general public component (a PSA) and a targeted, study-specific component, as evidenced by the public engagement strategy followed with convalescent plasma.

-Michelle

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, August 28, 2020 8:16 PM
To: Adam, Stacey (FNIH) [T] [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; McNay, Laura (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Bugin, Kevin (FDA/CDER) [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Erhardt, William (HHS/IOS) [b6]; Jim Neaton [b6]; Davey Smith [b6]; Tountas, Karen (FNIH) [T] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Wachtel, Jonathan <jwachtel@DELOITTE.com>; Chen, Helen Q. <qingchen@deloitte.com>; Payton, Manizhe (NIH/NIAID) [E] [b6]; Adedeji, Bola (NIH/NIAID) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]
Subject: RE: Discussion about Short Site Survey to Determine COVID Trial Burden

OK, here is what I came up with. Please let me know any major adjustments or things I forgot before I send to Francis and Janet. FYI I tried to lay this out as a logically/rhetorically sequenced argument rather than just record what people said in the order they said it. David

<ACTIV-2 and -3 Accrual Enhancement Discussion 8-28-20.docx>

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 8/31/2020 7:47:33 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: Discussion about Short Site Survey to Determine COVID Trial Burden
Attachments: ACTIV-2 and -3 Accrual Enhancement Discussion 8-28-20.docx

FYI: FC to talk to the ACTIV 2 & 3 study teams.

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, August 28, 2020 8:16 PM
To: Adam, Stacey (FNIH) [T] [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; McNay, Laura (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Bugin, Kevin (FDA/CDER) [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Erhardt, William (HHS/IOS) [b6]; Jim Neaton [b6]; Davey Smith [b6]; Tountas, Karen (FNIH) [T] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Wachtel, Jonathan <jwachtel@DELOITTE.com>; Chen, Helen Q. <qingchen@deloitte.com>; Payton, Manizhe (NIH/NIAID) [E] [b6]; Adedeji, Bola (NIH/NIAID) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]
Subject: RE: Discussion about Short Site Survey to Determine COVID Trial Burden

OK, here is what I came up with. Please let me know any major adjustments or things I forgot before I send to Francis and Janet. FYI I tried to lay this out as a logically/rhetorically sequenced argument rather than just record what people said in the order they said it. David

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/27/2020 6:19:17 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Checkboard not to be shared

Thanks, Ashley!

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 2:06 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Checkboard not to be shared

Hi Stacey,

No worries – I haven't shared this version w/o links with the war room yet but about to do this now and will cc you.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, August 27, 2020 2:04 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Checkboard not to be shared

Hi Ashley,

Thank you and sorry if I over stepped by flashing it up.

My apologies.

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 1:46 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: Checkboard not to be shared

Ashley Parker, Ph.D.

**Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines
(ACTIV)**

Office of the Director | National Institutes of Health

Tel: b6



National Institutes of Health

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/25/2020 6:15:32 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: ACTIV2 Central IRB Waiver Version 2

Thank you, Francis!

I know the team will be very appreciative! I will get this to them right away.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 2:05 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6];
McManus, Ayanna (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Adam,
Stacey (FNIH) [T] [b6]
Subject: RE: ACTIV2 Central IRB Waiver Version 2

Here you go.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, August 25, 2020 12:05 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6];
McManus, Ayanna (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Adam,
Stacey (FNIH) [T] [b6]
Subject: FW: ACTIV2 Central IRB Waiver Version 2

Hi Francis:

Regarding the local IRB waiver letter for ACTIV-2: As I mentioned on the daily active call this morning we have incorporated Carrie Wolinetz's suggestions and were just checking as a courtesy with Mike Lauer to see if there were folks other than the IRB Chairs we should send this to, but it has been over a day and Mike we know is very busy with

other things. We think the network leads will know where to take this, and meanwhile are getting pressure from OWS and ACTIV-2 reps to move this forward. Would it be possible therefore for you to sign this and return it to me today? Please copy Stacey Adam on the reply. Thanks, David

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/19/2020 5:44:41 PM
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CC: Leyva, Jessica M. [Infectious Diseases] [JMLeyva@mednet.ucla.edu]; Chen, Helen Q. [qingchen@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Treia (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dana Carluccio [b6]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Ginny Kan [b6]
Subject: ACTIV-2/-3 Trial Oversight Committee Meeting
Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20200819.pdf

Location: <https://fnih.zoom.us> b6

Start: 8/19/2020 7:00:00 PM

End: 8/19/2020 8:00:00 PM

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Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; b6; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Harrigan, Rachel (HHS/IOS); Erhardt, William (HHS/IOS)

Optional Attendees: Leyva, Jessica M. [Infectious Diseases]; Chen, Helen Q.; Wholley, David (FNIH) [T]; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Collins, Francis (NIH/OD) [E]; Dana Carluccio; Elsaid, Olivia; Church, Elizabeth (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Victoria Davey; Ginny Kan

Dear ACTIV-2/-3 TOC Members,

Please find attached the slides for today's meeting. We will be focusing mainly on discussing recruitment challenges for the trials. This will occur at the start of the meeting.

Thanks,
Stacey

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Dr Susanna Naggie, M.D.
[b6]

Subject: Summary of the February ACTIV Cross Trial Meeting
Attachments: 2021-02-26_Cross-Trial_Meeting_Summary.pdf

Dear ACTIV Trial Leads,

Please find attached the summary and action items from our call on Friday. I really appreciate all the great discussion. If you have any amendments or additions, please let us know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
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Subject: Follow up to ACTIV-3 Operations Team Meeting

Attachments: ACTIV3Operations4August2020.pdf

Dear ACTIV-3 Team,

As there were no pressing action items today from this meeting, I am simply distributing the slides that Jim shared. Please let us know if you have any pressing points to be addressed or if you have any comments.

As a reminder, we will be canceling this standing meeting moving forward, but we will schedule an operations team meeting ad hoc when needed.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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Sent: 2/26/2021 8:33:48 PM
To: UK-CTAPAdmin [UK-CTAPAdmin@ukri.org]; [REDACTED] Taylor, Charlotte [REDACTED]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Alison Cave - UKRI INNOVATEUK [REDACTED]; [REDACTED] Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Alastair Lamb [Alastair.Lamb@mrk.ukri.org]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; [REDACTED] Martin Landray [REDACTED] Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: COVID Therapeutics Pipeline for Trials

Dear UK colleagues:

As promised on our call back on February 10, we have created a secure data sharing site on a platform called Basecamp which can be used to share information between our groups on which agents have been reviewed as potential treatments / therapeutics for COVID-19. We have put up two folders on the site, one for U.S. data and one for U.K. data. The former is now populated with a summary of all agents that have been reviewed by the ACTIV Therapeutics-Clinical Agent Prioritization Sub Teams, and, thanks to the efforts of Alastair Lamb, the second folder is now populated with similar data from the UK effort. It is easy to upload new data as needed.

Below is an overview below of how to access the Basecamp site, which is quite simple: basically setting up a Basecamp account (if you do not already have one) and emailing Evan Appell (who is part of the Deloitte Consulting team working with FNIH) with that information once the account is established. The notes below include additional details on the materials that have already been uploaded to the ACTIV folder and instructions on how to upload other data that each member party would like to share with the broader group. (Note: The information and data on these sites is confidential, and therefore we request that you limit access to those in your organizations with a real need to see and use it.)

Please let us know if you have any questions or difficulty accessing the site, and our team can help to troubleshoot as needed.

I believe we had also agreed to continue meeting on roughly a monthly schedule; as I recall the UK team took the action item to set that up. I have not seen a meeting invitation yet, but please let us know if you need our assistance in getting that calendared.

Thank you again for your willingness to collaborate with ACTIV.

Best,
David

Accessing Basecamp:

1. In order to access Basecamp, the individual must **create an account** on Basecamp (*only if they do not have a Basecamp account already)

- This can easily be done by following this link:
https://3.basecamp.com/signup/account/new?plan=one_v1
- 2. Once the individual has created their account, they should inform the ACTIV team so that we can **grant them permission** to access the **“ACTIV / UK Data Sharing & Collaboration”** Basecamp site
 - The individual will then receive an email **directly from Basecamp** (not from FNIH) alerting them that they have been given access to the **“ACTIV / UK Data Sharing & Collaboration”** Basecamp site
- 3. Once the individual has been granted permission to the site, they can **access it through the email that was sent to them or by following this link:** <https://3.basecamp.com/3948057/projects/20877009>

Materials Available on the Basecamp site:

- 4. Once an individual enters the **“ACTIV / UK Data Sharing & Collaboration”** Basecamp site, they will see a **“Docs & Files”** folder which contains a **PowerPoint file** titled **“ACTIV_TX-Preclinical and Clinical_Agent Prioritization Summary_vSHARE”**
 - They can then download this file from Basecamp, and view it on their desktop app
- 5. The file includes a **summary of all agents that have been reviewed** by the ACTIV Therapeutics-Clinical Agent Prioritization Sub Teams.

A few brief notes on what is included in this file:

- There are ~200 reviews of Antiviral, Immune Modulator, and Symptomatic / Supportive agents that have been evaluated by ACTIV
- We have included a summary of the scoring criteria that were used to assess each agent at the very front of the deck
- There is a table of contents in the beginning of the deck listing all of the agents that have been reviewed (which also includes hyperlinks that can be used to navigate directly to the detailed review of any particular agent)
- 6. If an individual wishes to **upload any additional materials to the site to be shared with the group**, then they would enter the **“Docs & Files”** folder and select the **“+New”** button in the upper left corner of the screen to upload the relevant file

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8f06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina

[b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr], Nasr, Hana
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: Summary of the ACTIV-2/3 Trial Oversight Committee Meeting

Attachments: 2021-02-24_Trial_Oversight_Committee_Meeting_Summary.pdf

Dear ACTIV-2/3 TOC Members,

Please find attached the summary of our meeting yesterday. Thank you all for the good discussions. We have documented the decisions made within the notes for future reference. If you have any additions or amendments, please let us know.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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fnih.org

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 7/19/2020 7:37:17 PM
To: Robert Jan Benschoep [b6]; Daniel A Peterson [b6]; Charles T Benson [b6]; Kent P Hassett [b6]; Lilian Gonzalez [b6]; Andrew G Koustenis [b6]; Janice Evans [b6]; Jens Lundgren [b6]; Wentworth, Debby [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dc146ea82bb402cb5c6596f43056347-wentw001.um]; [b6]; [b6] Ajay Nirula - Lilly [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Andrew Phillips [b6]; Birgit Grund [b6]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; [b6]; [b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; [b6]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Ginny Kan [b6]; Baker, Jason [b6]; [b6]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]; [b6]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Mark Polizzotto [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Paul Klekotka - Lilly [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr bios]; Roger Paredes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Shweta Sharma [b6]; Taylor Thompson [b6]; [b6]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Davey, Victoria [b6]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.cabr]; Larson, Gregg [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c8ba84a1994b458f9c6ce304ea6b93-larso279.um]; Peter Smith, M.D. (Thoracic Surgery) [b6]; Katharina Krapp [b6]; John Rule [b6]; Aileen Ilaria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=860a21fece5d4ff2b206b3d1856c06cf-AileenIlari]; Simpson, Shelly (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=371206262b394fecaab6f43a3a6f9de6-shsimpson]; Vallee, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=560bbaaeb781440ea7c1ce8d8dc073a1-davidv.tmg-]; Lei Shen [b6]; Jenny Y Chien [b6]; Emmanuel Chigutsa [b6]; Daisy G Hartman [b6]; Jamie L Stack

[b6]; Kristina Southern Dinkel [b6]; Susan R Moriarty
[b6]; Gourab Datta [b6]; Judith Anne Gallagher
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Kousick [b6]; Harrington, Cristin A. [b6]; Huyen Cao
[b6]
CC: Janelle A Sabo [b6]; Carlos O Garner - Lilly [b6]; Chen, Helen Q.
[qingchen@deloitte.com]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Tountas, Karen (FNIH) [T]
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Marie Helleberg [b6]; Cate Carey [b6]; Vjecha, Michael
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(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 7/23/2020 11:11:38 AM
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CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: Letter of Support

Thank you, Francis, and thank you, Maria!

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: ([b6]) Mobile: ([b6])

From: Freire, Maria (FNIH) [T] ([b6])
Sent: Thursday, July 23, 2020 6:59 AM
To: Collins, Francis (NIH/OD) [E] ([b6])
Cc: Adam, Stacey (FNIH) [T] ([b6]); Tabak, Lawrence (NIH/OD) [E] ([b6]); Parker, Ashley (NIH/OD) [E] ([b6]); Menetski, Joseph (FNIH) [T] ([b6])
Subject: Re: Letter of Support

Terrific'. We will send it to OWS immediately. Thank you! M.

On Jul 23, 2020, at 6:57 AM, Collins, Francis (NIH/OD) [E] ([b6]) wrote:

Glad to do this, see attached.

FC

From: Freire, Maria (FNIH) [T] ([b6])
Sent: Thursday, July 23, 2020 5:22 AM
To: Collins, Francis (NIH/OD) [E] ([b6])
Cc: Tabak, Lawrence (NIH/OD) [E] ([b6]); Parker, Ashley (NIH/OD) [E] ([b6]); Menetski, Joseph (FNIH) [T] ([b6]); Adam, Stacey (FNIH) [T] ([b6])
Subject: Fwd: Letter of Support

Francis,

OWS is asking you to send a letter (attached) to ACTIV-2 sites - please see below. Is this something you want/can do? Stacey sent the email chain to her NIH contacts but there is urgency here. Joe will bring this up on the call today in case this email does not reach you before. M.

From: "Adam, Stacey (FNIH) [T]" [b6]
Date: Thursday, July 23, 2020 at 12:17:19 AM
To: "Gadbois, Ellen (NIH/OD) [E]" [b6] "Culp, Michelle (NIH/OD) [E]"
[b6]
Cc: "Menetski, Joseph (FNIH) [T]" [b6] "Freire, Maria (FNIH) [T]" [b6]
Subject: FW: Letter of Support

Hi Ellen and Michelle,

I was wondering if you could help me with the request described in the letter below.

In short the ACTIV-2 team is looking for Dr. Collins to sign a letter of support that could be distributed to the site PIs encouraging them to recruit to the trial.

Would this be something that you could assist with? Or would it be better if I reached out to Ashley Parker?

I am cc'ing Joe and Maria so perhaps they can mention this to Francis in the War Room tomorrow to pave the way.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, CPT Sheri (HHS/IOS) [b6]
Sent: Wednesday, July 22, 2020 11:13 AM
To: Adam, Stacey (FNIH) [T] [b6]

Cc: Bugin, Kevin (FDA/CDER) [b6]; Erhardt, William (HHS/IOS)

[b6]; Kim, Peter (NIH/NIAID) [E] [b6]

Subject: FW: Letter of Support

Good Morning, Stacey,

One of the outcomes in the ACTIV-2 and 3 review on Thursday with GEN Perna and Dr. Saloui was a letter of support to encourage facilities to support additional space for outpatient infusions for COVID-19+ patients as it was discovered that is one of the rate limiting steps to recruitment, especially in light of the four hour infusion cycle required for the first candidate.

As such, we worked with Peter and the site directors to draft a generic letter of support that will be sent to all site directors. The site director would then take it upon him or herself to draft a letter of specific recommendations to their leadership (to avoid forcing a single solution for all sites). The site directors that participated in the review all agreed that it would be more meaningful if the letter was signed by Dr. Collins. As such, Dr. Woodcock reached out to Dr. Collins and he agreed to do so.

I have attached the generic letter of support. Kevin suggested you would likely know the way to quickly staff this and have a recommendation for the appropriate letter \head.

Please note, the team recommended keeping the letter generic, because they wanted to get the letter out quickly as opposed to digging for addresses and having Dr. Collins sign multiple letters. We can always revisit this if a personal letter is warranted.

Please let me know how I can assist in pushing this forward.

Best,

Sheri

Sheri Parker, PMP, PhD

CAPT, MSC, USN

Therapeutics Clinical Operations Director

APAR0000005129

Operation Warp Speed

Cell: [b6]

From: Bugin, Kevin [b6]

Sent: Tuesday, July 21, 2020 8:41 PM

To: Parker, CPT Sheri (HHS/IOS)

Cc: Erhardt, William (HHS/IOS) [b6]

Subject: RE: Letter of Support

Hi Sheri,

I'd work with Stacey. She can utilize NIH channels. I think she can do it quickly.

Kevin

<ACTIV2 Infusion Needs.pdf>

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 7/12/2020 8:02:31 PM
To: Roger Paredes [b6]; Robert Jan Benschop [b6]; Jamie L Stack [b6]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Daniel A Peterson [b6]; Kent P Hassett [b6]; Lilian Gonzalez [b6]; Andrew G Koustenis [b6]; Janice Evans [b6]; Jens Lundgren [b6]; Wentworth, Debby [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dc146ea82bb402cb5c6596f43056347-wentw001.um]; [b6]; [b6]; Ajay Nirula - Lilly [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Andrew Phillips [b6]; Birgit Grund [b6]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; [b6]; m; Ginny Kan [b6]; Baker, Jason [b6]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]; [b6]; [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Mark Polizzotto [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Paul Klekotka - Lilly [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Shweta Sharma [b6]; Taylor Thompson [b6]; [b6]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Davey, Victoria [b6]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.cabr]; Larson, Gregg [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c8ba84a1994b458f9c6ce304ea6b93-larso279.um]; Peter Smith, M.D. (Thoracic Surgery) [b6]; Katharina Krapp [b6]; John Rule [John@napwha.org.au]; Aileen M Iaria [b6]; Simpson, Shelly (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=371206262b394fecaab6f43a3a6f9de6-shsimpson]; Vallee, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=560bbaaeb781440ea7c1ce8d8dc073a1-davidv.tmg-]; Charles T Benson [b6]; Lei Shen [b6]; Jenny Y Chien [b6]; Emmanuel Chigutsa [b6]; Daisy G Hartman [b6]; Kristina Southern Dinkel [b6]; Susan R Moriarty [b6]; Gourab Datta

b6; Judith Anne Gallagher b6; Patricia L Brown-Augsburger
b6
CC: Kenny, Dermot [dermot.kenny@novartis.com]; Pierson, Jerome (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddfa4630574f4cf794485d42e8f94f15-piersonjer];
b6; Ganapathy Gopalrathnam b6; Herpin, Betsey
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5f98ea94d0b549a9a20b14129958ffc8-herpinb]; Osborne, Cynthia (NIH) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=564d002f3a54421d90c6d86319e37c1f-osborneck]; Janelle A Sabo
b6; MacDonald, Leah (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=493f88a89a3543c0b01df5473fd7c08a-mgalcik]; Smolskis, Mary (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c85d8d087b304525ac6f2eab9fbb2d7-msmolskis]; Mock, Rebecca
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e7622242ed442a83557c86831344c5-sweetrl]; Proffitt, Calvin (NIH) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e6b92ae902c4ad3b388e4bd2f6e12da-proffittch]; Miller, Tracey (NIH) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9804c1bd1610470f91a91225da2f6182-trmiller]; Hensley, Lisa (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=083ee40b073846fdabb00489a21d8247-hensleyle]; Lau, Chuen-Yen
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2fd5052b609741d7a5560d4c68e30109-lauc]; Carlos O Garner - Lilly
b6; Cate Carey b6; Chen, Helen Q. [qingchen@deloitte.com];
Wachtel, Jonathan [jwachtel@DELOITTE.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh];
Desrosiers, Elizabeth A. b6; Kurilla, Michael (NIH/NCATS) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Daniel Dawson Murray
b6; Lisbeth Jørgensen b6; Nicole Engen
[wymann@umn.edu]; RH-FP-CHIP-ACTIV3-INSIGHT014 b6; Tierney,
John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Marie Helleberg
b6; Vjecha, Michael b6; Hudson, Fleur b6
Pett, Sarah b6; Bitten Aagaard b6; Charlotte Bjørnved Nielsen
b6; Eccard-Koons, Vanessa (NIH) [C] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78c68caa1a3e4beb87d31199d1566e39-eccardvs];
Buehn, Molly (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=42fe6790581143a78a8b68e17fc600c0-buehnmj]; Tonya L Combs
b6; Lori J Stephens b6; Barrett, Kevin (NIH/NIAID) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrett2]; Engel, Theresa (NIH) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Segal Raim, Sharon (NIH)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fec017d4c0f44cea96f9b89b4138b02d-segalsb]; Parrish, David (NIH/NIAID)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e43d7d2d97b44074abbca871c2e0fdd2-parrishdb]; Dighero-Kemp, Bonnie (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6dd7891a2804584a9743714a242bd6b-digherokemp]

Subject: ACTIV-3 Operations Team Meeting

Attachments: ACTIV_TX-Clinical_ACTIV-3 Operations Team Meeting Agenda_20200714.docx

Location: <https://fnih.zoom.us/j/92011111111> b6

Start: 7/14/2020 3:00:00 PM

End: 7/14/2020 4:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Tuesday from 11:00 AM to 12:00 PM

Required Attendees: Roger Paredes; Robert Jan Benschop; Jamie L Stack; Judy Currier; Daniel A Peterson; b6

Kent P Hassett; Lilian Gonzalez; Andrew G Koustenis; Janice Evans; Jens Lundgren; Wentworth, Debby;

b6; Ajay Nirula - Lilly; b6

Patterson, Amy (NIH/NHLBI) [E]; Andrew Phillips; b6

Birgit Grund b6; Lane, Cliff (NIH/NIAID) [E]; b6 Higgs, Elizabeth

(NIH/NIAID) [E]; b6 Ginny Kan; Baker, Jason;

b6 Neaton, Jim; b6

b6; Reineck, Lora (NIH/NHLBI) [E]; Kozak, Marina (OS/ASPR/BARDA); Miller, Marissa A

(NIH/NHLBI) [E]; Mark Polizzotto; b6 Proschan, Michael (NIH/NIAID)

[E]; Aggarwal, Neil (NIH/NHLBI) [E]; Paul Klekotka - Lilly; Harrigan, Rachel (HHS/IOS); Cavan, Reilly;

b6; Read, Sarah (NIH/NIAID) [E]; Shweta Sharma; Taylor Thompson; b6

b6 Rosenberg, Yves (NIH/NHLBI) [E]; Davey, Victoria; b6

Larson, Gregg; Peter Smith, M.D. (Thoracic Surgery); Katharina Krapp; John Rule; Aileen M Ilaria; Simpson, Shelly

(NIH) [C]; Vallee, David; Charles T Benson; Lei Shen; Jenny Y Chien; Emmanuel Chigutsa; Daisy G Hartman; Kristina

Southern Dinkel; Susan R Moriarty; Gourab Datta; Judith Anne Gallagher; Patricia L Brown-Augsburger

Optional Attendees: Kenny, Dermot; Pierson, Jerome (NIH/NIAID) [C]; b6 Ganapathy Gopalrathnam; Herpin,

Betsey (NIH/NIAID) [E]; Osborne, Cynthia (NIH) [C]; Janelle A Sabo; MacDonald, Leah (NIH) [C]; Galcik, Michael (NIH)

[C]; Smolskis, Mary (NIH/NIAID) [E]; Mock, Rebecca (NIH/NIAID) [E]; Proffitt, Calvin (NIH) [C]; Miller, Tracey (NIH) [C];

Hensley, Lisa (NIH/NIAID) [E]; Lau, Chuen-Yen (NIH/NIAID) [E]; Carlos O Garner - Lilly; Cate Carey, Chen, Helen Q.;

Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Parker,

Ashley (NIH/OD) [E]; Daniel Dawson Murray; Lisbeth Jørgensen; Nicole Engen; RH-FP-CHIP-ACTIV3-INSIGHT014;

Tierney, John (NIH/NIAID) [E]; Marie Helleberg; Vjecha, Michael; Hudson, Fleur; Pett, Sarah; Bitten Aagaard;

Charlotte Bjernved Nielsen; Eccard-Koons, Vanessa (NIH) [C]; Buehn, Molly (NIH) [C]; Tonya L Combs; Lori J Stephens;

Barrett, Kevin (NIH/NIAID) [E]; Engel, Theresa (NIH) [C]; Vogel, Susan (NIH/NIAID) [E]; Grace, Beth (NIH/NIAID) [C];

Hohn, Matt (NIH) [C]; b6 McNay, Laura (NIH/NIAID) [E]; Segal Raim, Sharon (NIH) [E]; Parrish,

David (NIH/NIAID) [E]; Dighero-Kemp, Bonnie (NIH/NIAID) [C]

Dear ACTIV-3 Operations Team,

Please see below and attached and below a draft agenda for Tuesday's meeting. Please let me know if you have any slides you would like to present for your sections.

Agenda Topic	Time (EDT)	Duration	Facilitator
Opening <ul style="list-style-type: none">Review Agenda and Meeting Objectives	11:00am –11:05am	5 min.	Jim

FDA Comments	11:05am – 11:25am	20 mins.	Jens
Update from Lilly Team on Drug Supply Plan and Timetable	11:25am – 11:35am	10 min.	Aileen
cIRB Discussion	11:35am – 11:45am	10 min.	Laura
Site Registration	11:45am – 11:55am	10 min.	Eileen
Recap & Next Steps	11:55am – 12:00pm	5 min.	Jim / Stacey

Thanks,
Stacey

Join Zoom Meeting

b6

Meeting ID: **b6**

Password: **b6**

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US (Germantown)

Dial by your location

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US (Germantown)
US (Chicago)
US (Houston)
US (San Jose)
US (San Jose)
US (Tacoma)

Meeting ID: **b6**

Password: **b6**

Find your local number: **b6**

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/24/2021 11:27:45 AM
To: [b6]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]; Leifer, Eric (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82f6ef6b63654d1294890664f81c9c95-leifere]; Wright, Clinton (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e18bd48748f4d7dab41338948aa9a59-wrightclb]; Scott Berry [b6]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; [b6]; [b6] Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; [b6]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; LaVange, Lisa M [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; [b6] Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Grund, Birgit [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2d226c78964db2a63a416a6acc2bae-birgit.umn.]; Hochman, Judith [b6]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Thomas Stock [b6]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; David Douglas [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]
CC: Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

Stacey

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Sent: 2/24/2021 11:27:39 AM
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CC: Dana Carluccio [b6]; Philip, Ritika [b6]; Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Dr Susanna Naggie, M.D. [b6]; Lawlor, Ciarán [b6] Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Rose Li Central Account [FNIH@roseliassociates.com]; Ramakrishnan, Raahul [b6] Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]

Subject: ACTIV Cross Trial Meeting

Location: [https://fnih.zoom.us/j/\[b6\]](https://fnih.zoom.us/j/[b6])

Start: 12/18/2020 1:30:00 PM

End: 12/18/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: Monthly
the last Friday of every 1 month(s) from 8:30 AM to 10:00 AM

Required [b6]; McNay, Laura (NIH/NIAID) [E]; Jim Neaton; Harrigan, Rachel (HHS/IOS);

Attendees: [b6] Douglas, David (HHS/IOS); [b6] Patterson, Amy (NIH/NHLBI) [E]; Thomas Stock; Birgit Grund; Hochman, Judith, Smith, David, Kim, Peter (NIH/NIAID) [E]; [b6] Javan, Arzhang (NIH/NIAID) [E]; [b6] Erhardt, William (HHS/IOS); LaVange, Lisa M, [b6] Jens Lundgren; Stock, Thomas (HHS/IOS), David Douglas; Proschan, Michael (NIH/NIAID) [E], [b6] Beigel, John (NIH) [E], Bozzette, Sam (NIH/NCATS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Bugin, Kevin (FDA/CDER), Lane, Cliff (NIH/NIAID) [E]; [b6] Michael Hughes; [b6] Kindzelski, Andrei (NIH/NHLBI) [E]; Judy Currier, Scott Berry; WahedA@edc.pitt.edu

Optional Attendees: Dana Carluccio; Philip, Ritika; Parker, CAPT Sheri (HHS/IOS); Elsaid, Olivia; Eric Hughes; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Wholley, David (FNIH) [T]; Teyhen, Deydre (HHS/IOS); Dr Susanna Naggie, M.D.; Lawlor, Ciarán; Lerner, Andrea (NIH/NIAID) [E]; Boucher, Cynthia (NIH/NCATS) [E]; Shipp, Allan (NIH/NHLBI) [E]; Rachel Harrigan; Nayak, Seema (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; qingchen@deloitte.com, Groesch, Mary (NIH/NHLBI) [E], Rose Li Central Account; Ramakrishnan, Raahul; Punturieri, Antonello (NIH/NHLBI) [E]

Dear ACTIV-1/2/3/4/5 Trial Leads,

Moving the December meeting up a week due to Christmas.

Thanks,
Stacey

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Sent: 7/15/2020 11:54:29 AM
To: Roger Paredes [b6]; Robert Jan Benschop [b6]; Jamie L Stack [b6]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Daniel A Peterson [b6]; Mark Polizzotto [b6]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Aileen Ilari [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=860a21fece5d4ff2b206b3d1856c06cf-AileenIlari]; Charles T Benson [b6]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kent P Hassett [b6]; Lilian Gonzalez [b6]; Andrew G Koustenis [b6]; Janice Evans [b6]; Jens Lundgren [b6]; Wentworth, Debby [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dc146ea82bb402cb5c6596f43056347-wentw001.um]; [b6]; [b6]; Ajay Nirula - Lilly [b6]; [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Andrew Phillips [b6]; Birgit Grund [b6]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; [b6]; Ginny Kan [b6]; Baker, Jason [b6]; Neaton, Jim [b6]; [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.ccbur um]; [b6]; [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; [b6]; [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Paul Klekotka - Lilly [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Shweta Sharma [b6]; Taylor Thompson [b6]; [b6]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Davey, Victoria [b6]; [vdavey@mail.va.gov]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.ccbur]; Larson, Gregg [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c8ba84a1994b458f9c6ce304ea6b93-larso279.um]; Peter Smith, M.D. (Thoracic Surgery) [b6]; Katharina Krapp [b6]; John Rule [b6]; Simpson, Shelly (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=371206262b394fecaab6f43a3a6f9de6-shsimpson]; Vallee, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=560bbaaeb781440ea7c1ce8d8dc073a1-davidv.tmg-]; Lei Shen [b6]; Jenny Y Chien [b6]; Emmanuel Chigutsa [b6]; [b6]; Daisy G Hartman [b6]; Kristina Southern Dinkel [b6]

b6 Susan R Moriarty b6 Gourab Datta
 b6 Judith Anne Gallagher b6 Patricia L Brown-Augsburger
 b6
 CC: Kenny, Dermot b6 Pierson, Jerome (NIH/NIAD) [C] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddfa4630574f4cf794485d42e8f94f15-piersonjer];
 b6 Ganapathy Gopalrathnam b6 Herpin, Betsey
 (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5f98ea94d0b549a9a20b14129958ffc8-herpinb]; Osborne, Cynthia (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 b6; MacDonald, Leah (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=493f88a89a3543c0b01df5473fd7c08a-mgalcik]; Smolskis, Mary (NIH/NIAD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c85d8d087b304525ac6f2eab9fbb2d7-msmolskis]; Mock, Rebecca
 (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e762224ed442a83557c86831344c5-sweetrl]; Proffitt, Calvin (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e6b92ae902c4ad3b388e4bd2f6e12da-proffittch]; Miller, Tracey (NIH) [C]
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=083ee40b073846fdabb00489a21d8247-hensleyle]; Lau, Chuen-Yen
 (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fd5052b609741d7a5560d4c68e30109-lauc]; Carlos O Garner - Lilly
 b6 Cate Carey b6 Eileen Denning b6
 Tierney, John (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Pett, Sarah
 b6; McNay, Laura (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Vogel, Susan (NIH/NIAD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=42fe6790581143a78a8b68e17fc600c0-buehnmj]; Daniel Dawson Murray
 b6; Grace, Beth (NIH/NIAD) [C] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Chen, Helen Q.
 [qingchen@deloitte.com]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Tountas, Karen (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A.
 b6; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Parker, Ashley
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Lisbeth Jørgensen
 b6; Nicole Engen b6 RH-FP-CHIP-ACTV3-INSIGHT014 [chip-
 b6; Marie Helleberg b6; Vjecha, Michael
 b6; Hudson, Fleur b6; Bitten Aagaard b6
 Charlotte Bjernved Nielsen b6; Eccard-Koons, Vanessa (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=78c68caa1a3e4beb87d31199d1566e39-eccardvs]; Tonya L Combs
 b6; Lori J Stephens b6; Barrett, Kevin (NIH/NIAD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrettk2]; Engel, Theresa (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 Raim, Sharon (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fec017d4c0f44cea96f9b89b4138b02d-segalsb]; Parrish, David (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e43d7d2d97b44074abbca871c2e0fdd2-parrishdb]; Dighero-Kemp, Bonnie
(NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b6dd7891a2804584a9743714a242bd6b-digherokemp]; Baseler, Beth (NIH)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2363525c118a468b9e8f5f61707c63f5-bbaseler]

Subject: Follow-up to ACTIV-3 Operations Team Meeting 07/14/2020

Attachments: ACTIV_Therapeutics-Clinical_Master Protocol Subgroup_ACTIV-3 Operations Team Meeting_20200714.pdf

Dear ACTIV-3 Operations Group,

Please find attached the summary of yesterday's call that Helen and Katharina were kind enough to capture for us.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: (b6) Mobile: (b6)

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNHI's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfc346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina

Subject: [b6] Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr], Nasr, Hana
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]
Attachments: 2021-02-17_Trial_Oversight_Committee_Meeting_Summary.pdf

Dear ACTIV-2/3 TOC Members,

Thank you for a great meeting on Wednesday. Please find the summary of the meeting attached.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] Mobile: [b6]
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika [b6]; Lawlor, Ciarán [b6]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris [b6]; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kueth, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Waring, Lorraine (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af91df8dec884f649cce10804470d1cb-Lorraine.Wa]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Nasr, Hana
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]; King,
Mason [b6]

Subject: Summary of the ACTIV Cross Trial Operations Strategy/Problem Solving Meeting
Attachments: ACTIV_Cross-Trial Ops Meeting_20210218.pdf

Dear ACTIV Trial Operations Leads,

Please find attached the summary of our meeting yesterday. Thank you all for your participation and the good discussion.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] Mobile: [b6]
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/17/2021 6:58:49 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Kelly Beazley [b6]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [dana.carluccio@roseliassociates.com]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina

[b6] Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr], Nasr, Hana
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: ACTIV-2/3 Trial Oversight Committee Meeting
Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210217.pdf
Location: <https://fnih.zoom.us> [b6]

Start: 2/17/2021 8:00:00 PM
End: 2/17/2021 9:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM
Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeiding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Neaton, Jim; Lundgren, Jens; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Kelly Beazley; Sorosa, Alex; Chen, Helen; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Dear ACTIV-2/3 TOC Members,

Please find attached the slides for today's meeting,

Thanks,
Stacey

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From: Woodcock, Janet [b6]
Sent: 6/12/2020 3:13:18 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Jens Lundgren [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [qingchen@deloitte.com]; Salathin, Carla [b6]; Lucas Smalldon [b6]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: RE: ACTIV mAb Steering Committee Meeting

OWS has been discussing this internally. We think we need to make sure the data are available to cross-walk the EP in the trials. jw

From: Bozzette, Sam (NIH/NCATS) [E] [b6]
Sent: Friday, June 12, 2020 11:11 AM
To: Adam, Stacey J (NIH) [b6]; Butterson, Joan [b6]; Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah W (NIH) [b6]; Karen Lynn Price [b6]; Higgs, Elizabeth S (NIH) [b6]; Woodcock, Janet [b6]; Stein, Peter [b6]; Carlos O Garner [b6]; Bugin, Kevin [b6]; Marks, Gilbert L (OS) [b6]; Farley, John [b6]; Jens Lundgren [b6]
Cc: Demarcus [b6]; Tountas, Karen H (NIH) [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley S (NIH) [b6]; Chen, Helen Q. [qingchen@deloitte.com]; Salathin, Carla [b6]; Lucas Smalldon [b6]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: RE: ACTIV mAb Steering Committee Meeting

All:

In some quarters, there continues to be a concern about the lack of harmonization across ACTIV 1 (the inpt immunomodulator protocol) and 3. Of course, I would not propose that either protocol change endpoints at this late date but think that we should be sure that we could construct 1's endpoints from 3's data (and vice-versa). Accordingly, I think that some sort of cross-walk between endpoints is in order. Since I am on the ACTIV1 writing team, I have already sent a note to this effect to them but nobody has had time to respond yet.

S

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] [b6]

Sent: Thursday, June 4, 2020 11:50 PM

To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; Judy Currier; Eric Hughes; LaVange, Lisa M; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER); Jens Lundgren

Cc: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Salathin, Carla; Lucas Smalldon; Dana Carluccio; Rose Li Central Account

Subject: ACTIV mAb Steering Committee Meeting

When: Friday, June 12, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/j/> [b6]

Dear ACTIV mAb Steering Committee,

Please find attached the agenda for tomorrow's meeting. As well as the current protocols for the ACTIV-2 and ACTIV-3 trials. They have not changed since Tuesday, but they are different from what we reviewed last week at our meeting, at least for ACTIV-3.

Thanks,
Stacey

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[b6] US (Houston)
[b6] US (San Jose)

Meeting ID: [b6]

Password: [b6]

Find your local number: <https://fnih.zoom.us/j/> [b6]

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/12/2020 3:17:33 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Jens Lundgren [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [qingchen@deloitte.com]; Salathin, Carla [b6]; Lucas Smalldon [b6]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: RE: ACTIV mAb Steering Committee Meeting
Attachments: ACTIV_TX-Clinical_mAb Steering Committee Meeting Agenda_20200612.pdf, INSIGHT014_ACTIV3_protocol_v0.4_8June2020.pdf; ACTIV-2-Redacted.pdf

Dear ACTIV mAb Steering Committee,

Please find attached the agenda for tomorrow's meeting. As well as the current protocols for the ACTIV-2 and ACTIV-3 trials. They have not changed since Tuesday, but they are different from what we reviewed last week at our meeting, at least for ACTIV-3.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/15/2020 3:30:05 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Jens Lundgren [b6]; Jim Neaton [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [gingchen@deloitte.com]; Salathin, Carla [b6]; Lucas Smalldon [b6]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Follow-up to ACTIV mAb Steering Committee Meeting 06/12/2020
Attachments: 2020-06-12_TX-Clinical_mAb_SC_Summary_v2.pdf

Dear ACTIV mAb Steering Committee,

Thank you all once again for a great meeting on Friday, and for all your help and counsel that you gave as we worked to get the initial designs for ACTIV-2 and ACTIV-3 together. While we will be transitioning the responsibilities of this committee to the new joint TOC for the trials, we will still be engaging all of you in other projects for ACTIV.

Thank you again for everything.

Please find attached the formal summary of Friday's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/13/2021 12:15:49 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8f06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfc346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina

Subject: [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]
Attachments: 2021-02-10_Trial_Oversight_Committee_Meeting_Summary.pdf; ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210210.pdf

Dear ACTIV-2/3 TOC Members,

Please find attached the summary and slides from our meeting on Wednesday.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] Mobile: [b6]
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/6/2020 8:36:55 PM
To: Jim Neaton [b6]; Jens Lundgren [b6]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; LaVange, Lisa M [b6]; Karen Lynn Price [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [b6]; William Erhardt [b6]; Gelijns, Annetine [b6]; Moskowitz, Alan [b6]; Ab Babiker [b6]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr bios]; Phillips, Andrew [b6]; [b6]; Birgit Grund [b6]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]; Joe Koopmeiners [b6]; David Vock [b6]; Thomas Murray [b6]; Max Parmar [b6]; Mark Polizzotto [b6]; Ginny Kan [b6]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [b6]; Roger Paredes [b6]; [b6]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; [b6]; [b6]
CC: Chen, Helen Q. [qingchen@deloitte.com]; Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Salathin, Carla [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Lucas Smalldon

b6

; Dana Carluccio

b6

; Bagiella, Emilia

b6

Subject: Follow-up to ACTIV-3 Writing Team and mAb Steering Committee Joint Meeting 06/05/2020

Attachments: GenericProtocolSummary5Junever0.2.pdf; INSIGHT014_ACTIV3_5June2020 (1).pdf; 2020-06-05_TX-Clinical_ACTIV-3_and_SC_Meeting_Summary.pdf

Dear mAb Steering Committee and ACTIV-3 Writing Team,

Please find attached the formal summary from our meeting yesterday, as well as the slides that Jens presented and the summary of the protocol as of 12pm yesterday.

This protocol summary and the protocol are still very much in draft and evolving the protocol team met again this morning and will meet tomorrow, as well. They are making lots of progress.

Thank you so much to the Steering Committee members for your feedback.

If you have any questions or amendments to the summary, please contact me.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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Donate to the FNHI's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



APAR0000005213

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/5/2020 3:12:23 AM
To: Jim Neaton [b6]; Jens Lundgren [b6]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; LaVange, Lisa M [b6]; Karen Lynn Price [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eada7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [b6]; William Erhardt [b6]; Gelijns, Annetine [b6]; Moskowitz, Alan [b6]; Ab Babiker [b6]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr bios]; Phillips, Andrew [b6]; Birgit Grund [b6]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]; Joe Koopmeiners [b6]; David Vock [b6]; Thomas Murray [b6]; Max Parmar [b6]; Mark Polizzotto [b6]; Ginny Kan [b6]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [b6]; Roger Paredes [b6]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; [b6]; [b6]
CC: Chen, Helen Q. [qingchen@deloitte.com]; Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Salathin, Carla [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Lucas Smalldon

b6

Dana Carluccio

b6

Bagiella, Emilia

Subject: Agenda for ACTIV-3 Writing Team and mAb Steering Committee Joint Meeting

Attachments: ACTIV_TX-Clinical_ACTIV-3 mAb Steering Committee Meeting Agenda_20200605.pdf

Dear mAb Steering Committee and ACTIV-3 Writing Team,

Please find attached the agenda for tomorrow. The ACTIV-3 team is diligently working to incorporate the feedback from today into the latest version of the protocol outline. Once they circulate this latest version I will send to this group tomorrow for review.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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Sent: 6/12/2020 3:04:25 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ARDS trial for Covid-19 patients

OH. If this is shared

-----Original Message-----

From: Wholley, David (FNIH) [T]
Sent: Friday, June 12, 2020 10:28 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ARDS trial for Covid-19 patients

No, we were asked to send out the survey to all of the EC and LT members. I will not list the survey however on public slides.

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, June 11, 2020 8:48 AM
To: Wholley, David (FNIH) [T] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: ARDS trial for Covid-19 patients

OK. I thought we are sending unsolicited request to the to the COVID candidate and technologies portal? Only following up with the survey for those that have been vetted by the NIH SMEs?

-----Original Message-----

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, June 10, 2020 10:56 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]
Subject: FW: ARDS trial for Covid-19 patients

I sent him the survey link.

-----Original Message-----

From: Rajin Ahuja [b6]
Sent: Tuesday, June 9, 2020 9:35 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: ARDS trial for Covid-19 patients

Dear Mr. Wholley,

Esther Krofah at FasterCures/Milken Institute gave me your name and I am reaching out for assistance with our recent attempt to apply for funding from BARDA. We realize the application portal just abruptly closed and are now looking for where to appropriately submit our grant application related to testing a potential COVID-19 treatment. We hope you might be able to advise where best to focus our effort, perhaps finding support through ACTIV.

I represent Biomarck Pharmaceuticals based in Durham, North Carolina. We have been conducting clinical trials (with previous NIH support) in acute respiratory distress syndrome (ARDS), chronic obstructive pulmonary disease (COPD), and non-small cell lung cancer (NSCLC), with a good safety profile in over 300 patients. Our seminal research explains the mode of action of our compound, BIO-11006, which inhibits the pro-inflammatory response of cells involved in the cytokine storm.

In February 2020, Biomarck was completing a phase 2 clinical trial for treating ARDS at four University referral hospitals. In coordination with the DSMB we ended the trial early due to ICUs being overwhelmed with COVID-19 patients. (NCT03202394) Data from this trial met the primary end point and demonstrated a 43% reduction in all cause mortality due to ARDS for ventilated patients. Unfortunately we have no way of knowing if any of those patients had coronavirus, so we would like to conduct further trials to see if BIO-11006 might be an effective treatment when given prior to, or after, patients are put on ventilators because of this virus or related lung injury.

As a small biopharmaceutical company with limited resources, we are excited about positive results in our well-conducted human trials thus far but equally frustrated with navigating a fast changing funding cycle. We need partners to help us gather further evidence about this potential treatment and to get that treatment to patients in need.

We have committed to trying to secure funding for phase 3 clinical trials, have designed ideal clinical trials, and have some study drug available to immediately begin treating patients with coronavirus and with the risk of developing ARDS lung disease. Of course we are inspired to move quickly during this

pandemic however, we have been working hard to understand the changing application portals at the NIH, now this week it appears BARDA is not the correct approach.

Can you please advise how ACTIV or other organizations might be able to help position our innovative research to actively study this potentially innovative treatment? We welcome any feedback or assistance for coordination that you may offer. Please don't hesitate to contact me by email or by phone. Thanks very much for your time and I have included the slide presentation from our initial BARDA meeting.

Kind regards,

Rajin Ahuja

Rajin Ahuja | Executive Chairman of the Board Biomarck Pharmaceuticals - 2530 Meridian Parkway Suite 300,
Durham, NC 27713
iPhone: [REDACTED] | [REDACTED] | biomarck.com

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/10/2020 4:11:41 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: Daily ACTIV Calls

Location: Dial-in: Passcode:

Start: 6/18/2020 4:15:00 PM

End: 6/18/2020 4:45:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Thursday from 2:30 PM to 3:00 PM

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Freire, Maria (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]

Dial-in:

Passcode:

Dr. Tabak as Leader:

Sent: 6/11/2020 11:49:39 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Higgins, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfde4719d7ac48e4a60b2ecd1969a716-higginsl]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponeim]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]
Subject: RE: Final ACTIV Slide Deck

Att

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, June 10, 2020 7:20 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]

[b6]; Adam, Stacey (FNIH) [T] <[b6]>; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; James, Stephanie (FNIH) [T] [b6]
Subject: RE: Final ACTIV Slide Deck

Hi Ashley,

Thanks for doing this – looks like a good summary of WG accomplishments and plans. Let's see what the WG leads say. Once they are OK with this, let's add to the slide set and plan to keep it updated.

Francis

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, June 10, 2020 5:46 PM
To: Collins, Francis (NIH/OD) [E] [b6] Myles, Renate (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E] [b6] Freire, Maria (FNIH) [T] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6] Fine, Amanda (NIH/OD) [E] [b6] Wojtowicz, Emma (NIH/OD) [E] [b6] Hallett, Adrienne (NIH/OD) [E] [b6] Higgins, Lauren (NIH/OD) [E] [b6] Gadbois, Ellen (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T] [b6] Gorman, Greta (FNIH) [T] [b6] Menetski, Joseph (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6] Tountas, Karen (FNIH) [T] [b6] Santos, Michael (FNIH) [T] [b6]; James, Stephanie (FNIH) [T] [b6]
Subject: RE: Final ACTIV Slide Deck

Hi Francis and Renate,

Please see attached (slide 9) draft accomplishments slide for the ACTIV deck.

The slide will need to be cleared by the FNIH team leads cc'd here of course and I am happy to work with FNIH offline to make any additional edits.

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, June 10, 2020 9:24 AM
To: Parker, Ashley (NIH/OD) [E] [b6] Myles, Renate (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E] [b6] Freire, Maria (FNIH) [T] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6] Fine, Amanda (NIH/OD) [E] [b6] Wojtowicz, Emma (NIH/OD) [E] [b6] Hallett, Adrienne (NIH/OD) [E] [b6] Higgins, Lauren (NIH/OD) [E] [b6] Gadbois, Ellen (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T] [b6] Gorman, Greta (FNIH) [T] [b6] Menetski, Joseph (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6] Tountas, Karen (FNIH) [T] [b6] Santos, Michael (FNIH) [T] [b6] James, Stephanie (FNIH) [T] [b6]
Subject: RE: Final ACTIV Slide Deck

Sure

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, June 10, 2020 8:08 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; James, Stephanie (FNIH) [T] [b6]
Subject: RE: Final ACTIV Slide Deck

Yes, I can help with pulling together a list of major accomplishments – maybe do this by WG?

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, June 10, 2020 6:24 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; James, Stephanie (FNIH) [T] [b6]
Subject: RE: Final ACTIV Slide Deck

Looks good, thanks for putting this together. I could imagine adding a slide at the end that lists major accomplishments. That would already be an interesting list (maybe Ashley would like to propose a draft?), and could be regularly updated.

FC

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, June 9, 2020 2:29 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; James, Stephanie (FNIH) [T] [b6]
Subject: Final ACTIV Slide Deck

Hi all:

Attached is the final ACTIV final deck, which we plan to share with the NIH institute and center communication directors for IC use. Please let us know at any time if these need to be updated so we can make sure ICs are using the latest information.

Best,
Renate

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Affairs
National Institutes of Health
[REDACTED] b6 [REDACTED]

b6

France
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Meeting ID: **b6**

Password: **b6**

Find your local number: <https://fnih.zoom.us> **b6**

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 6/5/2020 12:29:00 PM
To: Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Rashid, Kamilah (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58ce52e57bb74034834aa8660b5c8677-rashidkl]; Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2fbf13-walsher]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Christine – NIH OD has some progress underway with the COVID-19 portal/dahsboard and I think it would be good for them to share what they are already doing even if the Deloitte folks are still sketching their plan but if this is not of interest at this time defer to your preference here.

Thanks,
Ashley

From: Cutillo, Christine (NIH/NCATS) [E] [b6]
Sent: Friday, June 5, 2020 8:25 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Rashid, Kamilah (NIH/OD) [E] [b6]
Walsh, Elizabeth (NIH/OD) [E] [b6]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi All,

Can we schedule for mid-next week (e.g., Weds)? By that point the Deloitte folks should have a rough sketch of how our efforts can be streamlined and the processes needed; this should help our conversation a lot.

Best,
Christine

Christine Cutillo, MMCI
Special Assistant to the Director
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health

[b6]

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, June 4, 2020 9:28 PM
To: Rashid, Kamilah (NIH/OD) [E] [b6]; Walsh, Elizabeth (NIH/OD) [E] [b6]
Cutillo, Christine (NIH/NCATS) [E]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

I will try to find a time that works below with Christine's calendar and send the invite – thank you.

Ashley

From: Rashid, Kamilah (NIH/OD) [E] [b6]
Sent: Thursday, June 4, 2020 2:43 PM
To: Walsh, Elizabeth (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6];
Cutillo, Christine (NIH/NCATS) [E]
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

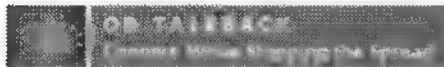
Hi Everyone,

My schedule is open except between 12 PM – 1 PM.

Best,
Kamilah

Kamilah Rashid, PharmD
Health Science Policy Analyst
Immediate Office of the Director
National Institutes of Health

M: [b6]
P: [b6]
E: [b6]



From: "Walsh, Elizabeth (NIH/OD) [E]" [b6]
Date: Thursday, June 4, 2020 at 2:30 PM
To: "Parker, Ashley (NIH/OD) [E]" [b6], "Cutillo, Christine (NIH/NCATS) [E]" [b6]
Cc: "Rashid, Kamilah (NIH/OD) [E]" [b6]
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi all,
I'm available in the 2-3:30 time slot.

Best,
Beth

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Thursday, June 4, 2020 at 2:22 PM
To: "Cutillo, Christine (NIH/NCATS) [E]" [b6]
Cc: "Rashid, Kamilah (NIH/OD) [E]" [b6], "Walsh, Elizabeth (NIH/OD) [E]" [b6]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Christine,

It was great touching base this morning and I wish we had more time. As promised, let's schedule a follow-up for tomorrow or early next week to discuss thoughts underway for connecting the dots between the COVID candidates/technologies portal and NCATS/ACTIV/Deloitte's efforts. It would be great for Beth and Kamilah to join, they lead the COVID-19 candidates/tech portal and want to ensure we are in sync as there is a request/need to track compounds after they are submitted by companies etc. in this portal.

I'm available tomorrow between 1:30-3:30pm if this works for everyone. I can also be available after 4:15pm tomorrow.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, June 4, 2020 10:18 AM
To: Cutillo, Christine (NIH/NCATS) [E] [b6]
Cc: Austin, Christopher (NIH/NCATS) [E] [b6]; Rashid, Kamilah (NIH/OD) [E]
[b6] Walsh, Elizabeth (NIH/OD) [E] [b6]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Christine,

Happy to chat – invite has been sent to discuss this morning.

Thanks,
Ashley

From: Cutillo, Christine (NIH/NCATS) [E] [b6]
Sent: Thursday, June 4, 2020 10:11 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Austin, Christopher (NIH/NCATS) [E] [b6]; Rashid, Kamilah (NIH/OD) [E]
[b6] Walsh, Elizabeth (NIH/OD) [E] [b6]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Ashley,

I'm not sure I understand what you mean by a few of your questions and comments. I think there is some misunderstanding about items. Would you be available sometime this morning to discuss? I can be available anytime before 12p.

What training and portal are you referring to? We have supported a few different ones, so your help on clarifying this will enable me to understand your questions better.

For items received through the OD portal – Deloitte/ACTIV has been planning on tracking the status of those that ACTIV receives, not however any of the items that are sent to RADx nor the ICs since it's not in their remit.

For the ACTIV compounds survey – this is just about to go out (it sounded like the emails were being finalized yesterday) and we starting discussing with the FNIH/Deloitte ACTIV teams about the process/procedure once they receive new compound suggestions from the OD portal (e.g., likely would need to be prioritized and then trigger the ACTIV compounds survey being sent). It sounds like this still needs to be determined, but Nina/Ben/Dina have it on their radar as an item to tackle next. The thing that Deloitte first needs to hash out is the data flow/schematic so that we can appropriately determine all the processes and procedures.

Best,
Christine

Christine Cutillo, MMCI
Special Assistant to the Director
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health

b6

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Wednesday, June 3, 2020 7:42 PM
To: Cutillo, Christine (NIH/NCATS) [E] b6
Cc: Austin, Christopher (NIH/NCATS) [E] b6 Rashid, Kamilah (NIH/OD) [E]
b6 Walsh, Elizabeth (NIH/OD) [E] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Christine,

As promised, please see the attached agents received by the COVID-19 portal May 23-May 29 and were selected by the NIH SMEs to move forward for ACTIV. 54 submissions were received in total.

NIH OD (Kamilah and Beth from Tara's team and myself) have a training scheduled tomorrow to learn more about the dashboard NCATS has funded. I still haven't quite yet wrapped my head around how all these things will be tracked. Francis is interested in knowing how we will be able to track all compounds that come in to the COVID-19 portal that is then shared with RADx, ACTIV, ICs, etc. – what happens to all of them if asked what happened with compound X? I assume this is the million dollar project.

I'm also aware if the 2nd tier portal/survey ACTIV and NCATS has developed for additional information but still not clear on how this will be handled for logistical/process purposes.

Christine – it would be useful if we could chat for 15-30 mins this week to touch base and discuss. Please let me know if your schedule allows.

Thank you,
Ashley

From: Austin, Christopher (NIH/NCATS) [E] b6
Sent: Monday, June 1, 2020 8:57 AM
To: Parker, Ashley (NIH/OD) [E] b6; Cutillo, Christine (NIH/NCATS) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6 Ford-Scheimer, Stephanie (NIH/NCATS) [C] b6
b6 Rashid, Kamilah (NIH/OD) [E] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Ashley,

Many thanks – this is just what we need and will be very useful for ensuring that our inventory process is comprehensive. In addition, the way the data are presented is quite good and will help us in our efforts to determine how to do that broadly.

All best,

Chris

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Sunday, May 31, 2020 8:48 PM
To: Austin, Christopher (NIH/NCATS) [E] [b6]; Cutillo, Christine (NIH/NCATS) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Ford-Scheimer, Stephanie (NIH/NCATS) [C] [b6]
[b6]; Rashid, Kamilah (NIH/OD) [E] [b6]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Chris and Christine,

Got it! Attached is the spreadsheet of emails received between early March and late May. With the [NIH COVID-19 Candidates and Technologies Portal](#) now live, all emails relevant to ACTIV are being routed there for submission and we've only had one round of review by the NIH COVID portal review group for inquiries received May 14-22 – please see 2nd attachment. The review group received a total of 58 submissions, 15 were determined to have potential – 8 of which are relevant to ACTIV.

Christine – I will cc you when we receive these each week. The 2nd attachment will provide an idea of the data fields used for the COVID portal.

We are still working on a process for receiving candidates from BARDA that have been reviewed by NIH staff who attend the BARDA held CoronaWatch meetings. Hopefully we can easily integrate those into a single spreadsheet to be shared. I've been working closely with Kamilah on Tara's team with this and we've discussed some of the questions outlined below –cc'ing Kamilah in case she has anything to add.

Thanks,
Ashley

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Sunday, May 31, 2020 11:18 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Cutillo, Christine (NIH/NCATS) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Ford-Scheimer, Stephanie (NIH/NCATS) [C] [b6]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Ashley,

Thank you for all your efforts and sorry for the delay in getting back to you; as you know, ACTIV has been busy!

Just want to clarify the portals issue. You're right that Larry has brought Deloitte in to do a larger assessment of COVID informatics needs since many ICs have asked for solutions; he and Susan G are leading that and there is a WG of us ICDs that will help. The immediate portal need is for ACTIV, to allow their prioritization teams, coordinated by Joe Menetski and Stacey Adam at FNIH, to have all the possible assays and agents to consider for inclusion. Christine Cutillo is working very closely with the FNIH and Deloitte teams to bring all the entries from many different portals into a single database. We want to be sure to include the entries that the OD portal is getting.

If you are sending all the submissions from the OD portal to FNIH already, the issue may have been solved indirectly already since the combined NIH-FNIH-Deloitte group has the OD entries. But it does appear quite odd for the NIH IC partners on ACTIV (coordinated by Christine Cutillo) to not receive NIH data from the OD, but rather have to get it from FNIH. Hence my request to simply get the information directly from you. To prevent any entries from falling through the cracks, pls begin copying Christine on the information you share with FNIH each week.

Hope this makes sense. Thanks,

Chris

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 20, 2020 7:12 PM
To: Cutillo, Christine (NIH/NCATS) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Austin, Christopher (NIH/NCATS) [E] [b6]; Santangelo, George (NIH/OD) [E] [b6]; Ford-Scheimer, Stephanie (NIH/NCATS) [C] [b6]; Gladman, Jordan (NIH/OD) [E] [b6]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Christine,

There have been a few updates since the note from Chris on Sunday and I want to clarify a few things.

- We have not received any spreadsheets from BARDA with data fields – one of the NIAID POs who is a reviewer for the BARDA CoronaWatch meetings shared a PDF short list of compounds for ACTIV Tx clinical WG to consider – this is what I shared on Friday.
- The spreadsheet OD has managed prior to the launch of the COIVD portal only contains emails (contact info, brief descriptor i.e. vaccine, preclinical interest, etc.) Dr. Collins has received as it relates to ACTIV. We have shared these with FNIH each week to sort and share relevant information with the WGs. ES has sent a standard response to those emails and in some cases FNIH has followed up when relevant. I think only a handful may have been fully useful and fleshed out.
- Tara's team is leading the NIH portal efforts – yes, data fields are closely aligned with BARDA. Also, Tara's team has a review process for queries received through this portal and would have the spreadsheet of data fields you are looking for – it may be a good idea to touch base with Tara and her team to ensure the efforts outlined below are aligned.
- As of yesterday, my understanding was Dr. Tabak made a decision to coordinate these efforts via a small IC data group and next steps are to bring in PM from Deloitte as you've indicated below to access all of the needs including RADx, ACTIV, and others before making a final decision to merge information from all portals. My take on this was to pause for the moment but I defer to Chris on the action items below.

I hope this is useful.

Best,
Ashley

From: Cutillo, Christine (NIH/NCATS) [E] [b6]
Sent: Wednesday, May 20, 2020 3:37 PM
To: Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]

Cc: Austin, Christopher (NIH/NCATS) [E] [b6] Santangelo, George (NIH/OD) [E]

[b6]

; Ford-Scheimer, Stephanie (NIH/NCATS) [C]

[b6]

Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Dear All,

Wanted to provide you with an update – we have been working with Andrew Derr (Deloitte NIH contract) to get someone by tomorrow/end of the week to start working on this. More detailed steps are included below in addition to a few questions. For clarification – which spreadsheet/database contains the appropriate data fields that should be propagated/mapped for each of the others (e.g., the BARDA submissions or the ACTIV compound spreadsheet)? I believe the NIH portal was built based on the BARDA submission data fields, but if we're ultimately aiming to connect to the ACTIV compound spreadsheet then potentially we should build toward that now when connecting these unsolicited submissions. Also, where do the submissions received via the NIH portal live and/or will a spreadsheet be sent at some periodicity? I apologize if these are questions that have already been addressed, but I haven't received that information yet.

Best,
Christine

1. Merge relevant information from all portals mapped to consistent data fields into the NIH db ("relevant" means submissions relevant to the ACTIV process; some NIH portals will contain COVID-related but not ACTIV-relevant entries)
 - a. BARDA submissions – ***is this the template of data fields that all others should be aligned with or should they be aligned with the data fields contained within the ACTIV compound spreadsheet?***
 - b. OD received submissions (prior to implementation of portal) – ***Ashely***, do you have this spreadsheet and have the data fields already been aligned with BARDA and/or the NIH portal?
 - c. NIAID submissions – spreadsheet provided by Alan Embry (contact him to ensure on same page); data fields need to be mapped/aligned
 - d. NCATS submissions – data fields need to be mapped/aligned
2. Eliminate duplicate entries (sent by the same person to multiple portals)
 - a. Via name/email matching
3. Send email to those not submitted through the NIH portal
 - a. Permission to integrate into ACTIV prioritization
 - b. Fill out survey – ***either compound RedCap survey or NIH portal depending on answer to initial question – thinking it's the former?***
4. Collate all into single db/spreadsheet for ACTIV/TransNIH use
5. Set up process for updating submissions received via NIH portal and other sources
 - a. ***Where do the submissions received via the NIH portal live and/or will a spreadsheet be sent at some periodicity?***
 - b. ***Has an email been sent out alerting folks at NIH to direct external inquiries to this portal or do we need to set up a process for receiving new submissions from e.g., NIAID?***

Christine Cutillo, MMCI
Special Assistant to the Director
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health

[b6]

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Sunday, May 17, 2020 12:37 PM
To: Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Cutillo, Christine (NIH/NCATS) [E] [b6]; Ford-Scheimer, Stephanie (NIH/NCATS) [C] [b6];
[b6]; Anderson, James (NIH/OD) [E] [b6]; Santangelo, George (NIH/OD) [E] [b6]
Subject: FW: BARDA Corona Watch | Therapeutic Candidates for Consideration

All,

We made good headway last week on a strategy to eliminate redundant entries from different submission portals to enable a complete and nonredundant list of entries to be provided to Stacey's group for wave 2 and wave 3 prioritization. The list from BARDA enclosed, and the analysis Stacey did on it, is just the kind of information we have, or need to extract, from the NIAID portal, NCATS portal, Bldg 1 portal, intramural portal, and nonpublic OPA db. The steps defined are:

1. Merge relevant information from all portals into the NIH db ("relevant" means submissions relevant to the ACTIV process; some NIH portals will contain COVID-related but not ACTIV-relevant entries)
2. Eliminate duplicate entries (sent by the same person to multiple portals) by name/email matching
3. Depending on whether the portal required the submitter to grant permission for sharing internal to NIH and/or with ACTIV (latter, non-NIH for evaluation purposes only, under NDA), send submitter an email asking for such permission to be granted, and
4. Depending on whether the submitter included the fields needed by Stacey's group for initial evaluation, in same email ask the submitter to supply the missing information
5. Collate responses and deliver to Stacey.

Christine, please devise a sequential workflow and enlist those you need for help.

Many thanks to all the portal owners for helping to create a filter funnel that will get the relevant information to ACTIV.

Chris

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Saturday, May 16, 2020 11:05 AM
To: Freire, Maria (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];
Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Maria,

Of the top three candidates we selected: Abatacept (CTLA-IgG1 Fusion), Cenicriviroc (CCR2/5 inhibitor), and Infliximab (TNF-alpha antagonist). Only the TNF inhibition seems to appear on the BARDA list.

Of our top 39 candidates that got scored, many MOAs were working to address some of the same issues that those on the BARDA list seem to target, such as anticoagulants, though those we reviewed and selected were largely already available in hospitals so they could be easily and quickly deployed for the NHLBI/NINDS trial. BARDA's anticoagulants seem to be next generation and working through slightly different MOAs. Also, we had a number of anti-inflammatory targeting MOAs on our list that don't appear on the BARDA list, such as anti-IL17, RAS inhibition, PDE4 inhibition, GSK-3

inhibition, and others. But again, both groups trying to get at the same issue, just through different points in the inflammation pathway. The one thing I notice is the BARDA list only seems to have 1 antiviral on their list, whereas we have about 9, and while we didn't prioritize them first, we did think some would likely be high priority for our next wave of trials with a slightly different design.

Again, I hope this is helpful.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Freire, Maria (FNIH) [T] [b6]

Sent: Saturday, May 16, 2020 10:51 AM

To: Adam, Stacey (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]

Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]

Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]

Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Thank Stacey- very helpful. How about the converse: are there MOA on the WG list that are not on this one? M.

From: "Adam, Stacey (FNIH) [T]" [b6]

Date: Saturday, May 16, 2020 at 9:40:55 AM

To: "Freire, Maria (FNIH) [T]" [b6]; "Collins, Francis (NIH/OD) [E]" [b6]

Cc: "Parker, Ashley (NIH/OD) [E]" [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]

"Lane, Cliff (NIH/NIAID) [E]" [b6]; "Austin, Christopher (NIH/NCATS) [E]" [b6]

"Anderson, James (NIH/OD) [E]" [b6]; "Wholley, David (FNIH) [T]" [b6]

Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Maria and Francis,

As these compounds largely did not have information in the public domain for ongoing trials or major preclinical experiments in SARS-CoV-2 when we did our first pull 5 weeks ago, most, if not all, would not have been on our list.

However, looking at the mechanisms of action (MOA), we did have a number of agents that have same or similar MOAs, including IL-6 inhibition (3 agents on our review list) and JAK/STAT inhibitors (4 on our list). Both of these classes our group chose not to select for the first large confirmatory trial we were designing because their MOAs were being studied in well designed trials by other groups.

There are some MOAs that were not on our original list, such as IL-15 inhibition, though we did have many other IL inhibitors, including IL-1, 6, and 17. The Syk inhibitors are also a new MOA that did not appear in the first 170 of clinically ready agents.

I hope this information helps.

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Freire, Maria (FNIH) [T] [b6]
Sent: Saturday, May 16, 2020 10:03 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];
Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6];
Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Adam,
Stacey (FNIH) [T] [b6]
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Good morning Stacey. Could you please take a look and let us know? Many thanks, M.

On May 16, 2020, at 8:46 AM, Collins, Francis (NIH/OD) [E] <[b6]> wrote:

Interesting. Would the therapeutics on this list have been on the list of 170 that the Therapeutics Clinical WG was prioritizing?

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 2:49 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane,
Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson,
James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH)
[T] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]
Subject: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi all,

Attached is a list of compounds shared by one of NIAID's program officers, Steve Smiley who is a reviewer/participant assigned to the **therapeutics Tech Watch (now CoronaWatch) meetings** at BARDA. Steve indicated they have ~10 meetings per week and there are other NIAID experts who join these. He suggested NIH reps who attend the BARDA meetings could assist with sharing compounds with ACTIV – recent focus has been on therapeutic products for infected outpatients for the DAIDS ACTG network but he indicated many products are better suited to phase 2 testing in hospitalized patients.

Steve also suggested we develop a short script for the NIH POCs who attend the BARDA Corona Watch meetings and use this as an opportunity to inform companies about ACTIV. We could link them to our vetting process (i.e. new portal) and/or feed them directly to the working groups. It seems prior to ACTIV, NIAID has used these Corona watch meetings to look for opportunities that would be useful for NIAID networks – Cliff likely has more insight here. The opportunity to expand and be inclusive of ACTIV seems like the right path and an opportunity to stay connected with what comes through BARDA.

Would this be something of interest to the group?

Thanks,

Sent: 6/3/2020 1:06:34 PM
To: Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2fbf13-walsher]; Rashid, Kamilah (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58ce52e57bb74034834aa8660b5c8677-rashidkl]
Subject: RE: Re ACTIV | Submissions from COVID-19 Candidates and Technologies Portal

Hi

From: Walsh, Elizabeth (NIH/OD) [E] [b6]
Sent: Wednesday, June 3, 2020 8:58 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Rashid, Kamilah (NIH/OD) [E] [b6]
Subject: Re: Re ACTIV | Submissions from COVID-19 Candidates and Technologies Portal

Hi Ashley,

We're going to set something up on the reviewer site to track what happens with the information coming in from the portal.

Best,
Beth

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Wednesday, June 3, 2020 at 8:08 AM
To: "Walsh, Elizabeth (NIH/OD) [E]" [b6], "Rashid, Kamilah (NIH/OD) [E]" [b6]
Subject: Re ACTIV | Submissions from COVID-19 Candidates and Technologies Portal

Good morning Beth and Kamilah,

We will receive the portal submissions every week, right? Likely on Wednesdays?

What 's the verdict for tracking candidates from entry to the end? Will Tara prefer to implement into the current platform or defer to NCATS?

Thanks!
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, June 3, 2020 8:05 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV | Submissions from COVID-19 Candidates and Technologies Portal

Hi Ashley, how often will we be getting these submissions? Thanks

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 27, 2020 3:12 PM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]

Cc: Collins, Francis (NIH/OD) [E] [b6] Tabak, Lawrence (NIH/OD) [E] [b6]

Subject: ACTIV | Submissions from COVID-19 Candidates and Technologies Portal

Good afternoon,

Please see the attached cleared submissions that came through the NIH COVID-19 Candidates and Technologies Portal, May 14-22 and were vetted by the NIH COVID portal review group (a group of SMEs). The review group received a total of 58 submissions, 15 were determined to have potential – 8 of which are relevant to ACTIV for therapeutics, vaccines, and clinical trial capacity.

Based on the discussions during the preclinical working group meeting today – hopefully this will help with targeting the more detailed application/questionnaire in progress to relevant companies/partners.

Best,
Ashley

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 2/12/2021 3:02:57 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]

Subject: Canceled: ACTIV Call "War Room"

Location: Dial-In: Passcode:

Start: 2/15/2021 1:00:00 PM

End: 2/15/2021 1:30:00 PM

Show Time As: Free

Recurrence: Weekly
every Monday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David (FNIH) [T], Collins, Francis (NIH/OD) [E], Tabak, Lawrence (NIH/OD) [E], Anderson, James (NIH/OD) [E], Parker, Ashley (NIH/OD) [E], Lane, Cliff (NIH/NIAID) [E], Rutter, Joni (NIH/NCATS) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E], McManus, Ayanna (NIH/OD) [E], Burrus-Shaw, Cyndi (NIH/OD) [E], Simon, Dina (NIH/OD) [C], Hughes, Karen (NIH/OD) [E], Carver, Trea (NIH) [C], Sepulveda, Dorina (FNIH) [T], Patterson, Amy (NIH/NHLBI) [E], Adam, Stacey (FNIH) [T], Dimishkov, Roxanne (NIH/NHLBI) [C], Freire, Maria (FNIH) [T]

Extending to end of December

Dial-in: b6

Passcode: b6

Dr. Tabak as Leader: b6

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/2/2020 3:42:46 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Lawlor, Ciarán [b6]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Chen, Helen [qingchen@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]
Subject: HOLD: ACTIV-OWS mAb Clinical Summit
Location: Zoom invite (to be sent)
Start: 6/9/2020 4:00:00 PM
End: 6/9/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Wholley, David; Adam, Stacey (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Woodcock, Janet (FDA/CDER); Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Menetski, Joseph; Bugin, Kevin (FDA/CDER); Lawlor, Ciarán
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Thomas, Ashley (FDA/CDER); Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan

Sent: 6/2/2020 12:46:23 PM
To: Pollock, Rachel (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc];
Subject: RE: ACTIV Invitations for Leadership Meeting 6/3

Thanks! We need to

From: Pollock, Rachel (NIH/OD) [E] [b6]
Sent: Tuesday, June 2, 2020 7:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E]
[b6]
Subject: Re: ACTIV Invitations for Leadership Meeting 6/3

Thanks, Ashley. We'll take a look.

Rachel Pollock

O: [b6]
C: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, June 2, 2020 4:34:53 AM
To: Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E]
[b6]
Subject: Fwd: ACTIV Invitations for Leadership Meeting 6/3

Good morning,

Please see below.

Thank you,
Ashley

Begin forwarded message:

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: June 1, 2020 at 9:03:14 PM EDT
To: "Wholley, David (FNIH) [T]" [b6]; "Parker, Ashley (NIH/OD) [E]" [b6]
Cc: "Melencio, Cheryl (FNIH) [T]" [b6]; "Adam, Stacey (FNIH) [T]" [b6]
"Menetski, Joseph (FNIH) [T]" [b6]; "Tountas, Karen (FNIH) [T]" [b6]
"Santos, Michael (FNIH) [T]" [b6]; "Allen-Gifford, Patrice (NIH/OD) [E]" [b6]
[b6]
Subject: RE: ACTIV Invitations for Leadership Meeting 6/3

I also thought we reached out to Lepore and Reese, but I can't locate those e-mails. I'm looping in Exec Sec to see if they can find something.

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, June 1, 2020 6:10 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E]
[b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Menetski, Joseph (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Santos, Michael (FNIH) [T] [b6]
Subject: RE: ACTIV Invitations for Leadership Meeting 6/3

I thought we had invited John Lepore from GSK and David Reese from Amgen? If not, we should. I would not invite BMGF – their relationship as observer is clear, and we could certainly ask about Evotech, since Kara Carter has been very good from what I have heard.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, June 1, 2020 5:37 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]
Subject: Re: ACTIV Invitations for Leadership Meeting 6/3

Hi Francis and David,

We did not have the opportunity to discuss the difference between participants and ACTIV leadership orgs on the 5/21 war room call – Francis was unexpectedly pulled into another meeting. A small number of companies/foundations were not originally listed as leadership partners with ACTIV, therefore they were not included in previous leadership meetings. As of May 20th, we currently have all partners listed on the ACTIV webpage as leadership.

I wanted to raise the question – do we need to invite a member from Amgen, Evotec, GSK, and BMGF to the leadership meeting on Wednesday and include for future meetings?

Thank you,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 20, 2020 10:51 AM
To: Wholley, David (FNIH) [T] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]
Subject: Re: FOR YOUR REVIEW: ACTIV Web Page Updates

Hi David,

OCPL is in the process of finalizing the [ACTIV webpage](#) and Francis asked to include BMGF as a non-profit organization and I let him know they are not one of the “leadership organizations”, along with a few companies, and academics which are not included. Francis would like to discuss on our war room call tomorrow morning – he’s not clear on the distinction between participants and leadership group members.

I’ve worked with Cheryl to figure out who is currently on the leadership list and identified who is not to help with sorting this out.

Non leadership partners:

1. Companies: (Amgen, Evotec, GSK) – seems there should be more here?
2. Non-profits: BMGF
3. Academics: all

Leadership partners:

1. 7 government: NIH, FDA, BARDA, CDC, VA, DOD, EMA,
2. 16 companies: Pfizer, AbbVie, Eisai, Gilead, KSQ Therapeutics, AstraZeneca, Roche/Genentech, Karuna Therapeutics, Merck, Takeda, Sanofi, Eli Lilly, J&J, Novartis, BMS, Vir Bio
3. Non-profit: FNIH, Fred Hutchinson Cancer Research Center, RTI International

All companies along with BMGF are listed on the [ACTIV webpage](#). Depending on the outcome of our discussion tomorrow, we may need to change the language on the webpage.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 20, 2020 10:02 AM
To: Parker, Ashley (NIH/OD) [E] [b6] Myles, Renate (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: ACTIV Web Page Updates

I guess I'm not quite clear on the distinction between participants and leadership group members. Maybe we can discuss at our next War Room conversation?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 20, 2020 9:57 AM
To: Myles, Renate (NIH/OD) [E] [b6] Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: ACTIV Web Page Updates

Hi Francis and Renate,

Francis – we originally decided not to include all organizations represented on the WGs for the list of “leadership organizations” – BMGF, a small group of companies, and academics are not included.

Is the preference to list BMGF as a leadership organization? If so, we will need to invite someone from BMGF to join the ACTIV leadership group.

Looks great, Renate. The new EC members: Gary Disbrow, BARDA; Peter Marks, FDA; Andrew (Andy) Plump, Takeda.

Thank you,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Wednesday, May 20, 2020 8:05 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
[b6]
Cc: Burklow, John (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E]
[b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: ACTIV Web Page Updates

Great, thanks Francis. I'll add BMGF.

Ashley: would you send me the list of the additional EC members?

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 20, 2020 6:44 AM
To: Myles, Renate (NIH/OD) [E] [b6] Tabak, Lawrence (NIH/OD) [E]
[b6]
Cc: Burklow, John (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E]
[b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: ACTIV Web Page Updates

Looking good. I prefer the org chart with rectangles instead of circles. Note that we are adding three more members to the Exec Comm today, and that will need to be reflected. I also think we should include BMGF in the non-profit category – they have reps on three of the WGs and have been engaged.

FC

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, May 19, 2020 9:40 PM
To: Collins, Francis (NIH/OD) [E] [b6] Tabak, Lawrence (NIH/OD) [E]
[b6]
Cc: Burklow, John (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E]
[b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: FOR YOUR REVIEW: ACTIV Web Page Updates

Hi Francis and Larry:

We soft launched the [ACTIV webpage](#) pretty quickly with the intention of spiffing it up a bit with a little more time. Attached is a PDF version of the website with a few graphical touches to the main and leadership pages, and another PDF with slightly revised presentation of the organization chart. Let me know if the treatment and images look okay to you and we'll have the online branch incorporate them on the page. Once completed, we'll do a harder launch of the webpage with a feature on the [NIH gov](#) homepage and some social media promotion.

Thanks,
Renate

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/2/2020 7:47:30 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 6/11/2020 12:00:00 PM

End: 6/11/2020 12:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Thursday from 2:30 PM to 3:00 PM

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Freire, Maria (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/1/2020 1:15:49 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]

Subject: Pre-call for ACTIV Leadership Call #4
Location: see webex below

Start: 6/1/2020 8:00:00 PM
End: 6/1/2020 9:00:00 PM
Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Santos, Michael (FNIH) [T]; Tountas, Karen (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

Join Webex meeting

Meeting number (access code): **b6** Meeting password: **b6**

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Tap to call in from a mobile device (attendees only)

[b6] Call-in toll number (US/Canada)

Global call-in numbers

Join using Microsoft Lync or Microsoft Skype for Business

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Get Lync for free

If you are a host, click here to view host information. IMPOR

Meeting ID: [b6]

Password: [b6]

Find your local number: <https://fnih.zoom.us> [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/30/2020 9:29:17 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 4/24/2020 12:00:00 PM

End: 4/24/2020 12:30:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Friday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E];

Freire, Maria (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina

(NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/30/2020 9:28:45 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 5/6/2020 12:00:00 PM

End: 5/6/2020 12:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Freire, Maria (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/30/2020 9:28:19 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 5/5/2020 12:00:00 PM

End: 5/5/2020 12:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Tuesday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David (FNIH) [T], Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E];

Austin, Christopher (NIH/NCATS) [E]; Freire, Maria (FNIH) [T], Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E], Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/30/2020 9:27:36 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 5/4/2020 12:00:00 PM

End: 5/4/2020 12:30:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Monday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E];

Austin, Christopher (NIH/NCATS) [E]; Freire, Maria (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina

(NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]

Sent: 5/29/2020 1:04:45 PM

To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Hughes, Eric [eric.hughes@novartis.com]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremcc]

CC: Earle, Melody (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6511f04014a749a78e9243ec427ae7fc-earlem2]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: Linking Up NHLBI COVID Plans and ACTIV Plans

Location: see webex below

Start: 6/5/2020 4:30:00 PM

End: 6/5/2020 5:30:00 PM

Show Time As: Tentative

Required Attendees: Wholley, David; Adam, Stacey (FNIH) [T]; Read, Sarah (NIH/NIAID) [E]; Hughes, Eric; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Kiley, James (NIH/NHLBI) [E]; Hoots, W. Keith (NIH/NHLBI) [E]; Freire, Maria (FNIH) [T]

Optional Attendees: Earle, Melody (NIH/NHLBI) [E]; Hill, Zoe (NIH/NHLBI) [C]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Simon, Dina (NIH/OD) [C]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]

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Sent: 5/29/2020 6:37:11 PM
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Francis and Larry,

From: Freire, Maria (FNIH) [T] [b6]
Sent: Saturday, May 16, 2020 11:09 AM
To: Adam, Stacey (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];
Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6];
Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Great analysis, Stacey. Many thanks, M.

From: "Adam, Stacey (FNIH) [T]" [b6]
Date: Saturday, May 16, 2020 at 10:05:25 AM
To: "Freire, Maria (FNIH) [T]" [b6]; "Collins, Francis (NIH/OD) [E]" [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6];
"Lane, Cliff (NIH/NIAID) [E]" [b6]; "Austin, Christopher (NIH/NCATS) [E]" [b6]
"Anderson, James (NIH/OD) [E]" [b6]; "Wholley, David (FNIH) [T]" [b6]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Maria,

Of the top three candidates we selected: Abatacept (CTLA-IgG1 Fusion), Cenicriviroc (CCR2/5 inhibitor), and Infliximab (TNF-alpha antagonist). Only the TNF inhibition seems to appear on the BARDA list.

Of our top 39 candidates that got scored, many MOAs were working to address some of the same issues that those on the BARDA list seem to target, such as anticoagulants, though those we reviewed and selected were largely already available in hospitals so they could be easily and quickly deployed for the NHLBI/NINDS trial. BARDA's anticoagulants seem to be next generation and working through slightly different MOAs. Also, we had a number of anti-inflammatory targeting MOAs on our list that don't appear on the BARDA list, such as anti-IL17, RASPI inhibition, PDE4 inhibition, GSK3 inhibition, and others. But again, both groups are trying to get at the same issue, just through different points in the inflammation pathway. The one thing I notice is the BARDA list only seems to have 1 antiviral on their list, whereas we have about 9, and while we didn't prioritize them first, we did think some would likely be high priority for our next wave of trials with a slightly different design.

Again, I hope this is helpful.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Freire, Maria (FNIH) [T] [b6]
Sent: Saturday, May 16, 2020 10:51 AM
To: Adam, Stacey (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Thank Stacey- very helpful. How about the converse: are there MOA on the WG list that are not on this one? M.

From: "Adam, Stacey (FNIH) [T]" [b6]
Date: Saturday, May 16, 2020 at 9:40:55 AM
To: "Freire, Maria (FNIH) [T]" [b6]; "Collins, Francis (NIH/OD) [E]" [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]
"Lane, Cliff (NIH/NIAID) [E]" [b6]; "Austin, Christopher (NIH/NCATS) [E]" [b6]
"Anderson, James (NIH/OD) [E]" [b6]; "Wholley, David (FNIH) [T]" [b6]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Maria and Francis,

As these compounds largely did not have information in the public domain for ongoing trials or major preclinical experiments in SARS-CoV-2 when we did our first pull 5 weeks ago, most, if not all, would not have been on our list.

However, looking at the mechanisms of action (MOA), we did have a number of agents that have same or similar MOAs, including IL-6 inhibition (3 agents on our review list) and JAK/STAT inhibitors (4 on our list). Both of these classes our group chose not to select for the first large confirmatory trial we were designing because their MOAs were being studied in well designed trials by other groups.

There are some MOAs that were not on our original list, such as IL-15 inhibition, though we did have many other IL inhibitors, including IL-1, 6, and 17. The Syk inhibitors are also a new MOA that did not appear in the first 170 of clinically ready agents.

I hope this information helps.

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Freire, Maria (FNIH) [T] [b6]
Sent: Saturday, May 16, 2020 10:03 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Adam,
Stacey (FNIH) [T] [b6]
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Good morning Stacey. Could you please take a look and let us know? Many thanks, M.

On May 16, 2020, at 8:46 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Interesting. Would the therapeutics on this list have been on the list of 170 that the Therapeutics Clinical WG was prioritizing?

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 2:49 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]
Subject: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi all,

Attached is a list of compounds shared by one of NIAID's program officers, Steve Smiley who is a reviewer/participant assigned to the **therapeutics Tech Watch (now CoronaWatch) meetings** at BARDA. Steve indicated they have ~10 meetings per week and there are other NIAID experts who join these. He suggested NIH reps who attend the BARDA meetings could assist with sharing compounds with ACTIV – recent focus has been on therapeutic products for infected outpatients for the DAIDS ACTG network but he indicated many products are better suited to phase 2 testing in hospitalized patients.

Steve also suggested we develop a short script for the NIH POCs who attend the BARDA Corona Watch meetings and use this as an opportunity to inform companies about ACTIV. We could link them to our vetting process (i.e. new portal) and/or feed them directly to the working groups. It seems prior to ACTIV, NIAID has used these Corona watch meetings to look for opportunities that would be useful for NIAID networks – Cliff likely has more insight here. The opportunity to expand and be inclusive of ACTIV seems like the right path and an opportunity to stay connected with what comes through BARDA.

Would this be something of interest to the group?

Thanks,
Ashley

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/22/2020 7:50:45 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Chen, Helen [qingchen@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
Subject: ACTIV EC Pre-call
Location: see webex below
Start: 6/15/2020 8:15:00 PM
End: 6/15/2020 9:00:00 PM
Show Time As: Tentative

Required Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

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Global call-in numbers

Join using Microsoft Lync or Microsoft Skype for Business

Dial [b6]@lync webex .com

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If you are a host, go here to view host information. [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/22/2020 1:55:21 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: ACTIV War Room Call -- Saturday, May 23, 2020

Location: Dial-in: [b6] Passcode: [b6]

Start: 5/23/2020 3:00:00 PM

End: 5/23/2020 3:45:00 PM

Show Time As: Tentative

Required Attendees: Wholley, David, Collins, Francis (NIH/OD) [E], Tabak, Lawrence (NIH/OD) [E], Lane, Cliff (NIH/NIAID) [E], Freire, Maria (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E], Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

Sent: 5/21/2020 3:53:56 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: FW: Action Items from 5/20 ACTIV Executive Committee Teleconference
Attachments: 5.20 ACTIV Executive Committee Meeting Action Items_20200521 v2 (002).pptx

Hi Jill,

I think FC can share this with the Secretary – can we rem

From: Melencio, Cheryl (FNIH) [T] [b6] } **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Thursday, May 21, 2020 11:32 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: Action Items from 5/20 ACTIV Executive Committee Teleconference

Dear ACTIV Executive Committee members, Working Group Co-chairs, and other meeting participants:

As promised, please see the action items from yesterday afternoon's ACTIV EC meeting. Please let us know anything we may have missed.

In addition, we have captured and plan to address those comments and suggestions that were entered into the chat box in the meeting and not otherwise addressed in the course of the discussion, and will also be sending along the complete meeting notes soon.

Regards,
David

David Wholley
Senior Vice President, Research Partnerships
Foundation for the National Institutes of Health

Password: b6

Find your local number: <https://fnih.zoom.us> b6

Sent: 5/20/2020 2:13:56 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: FW: EC ACTIV meeting

Hi Cheryl,

I let John know that Carrie is included in the EC call today and future meetings. Can we please add John Burklow and Renate Myles to the EC call today and future meetings?

-----Original Message-----

From: Burklow, John (NIH/OD) [E] [b6]
Sent: Wednesday, May 20, 2020 9:57 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: EC ACTIV meeting

Hi, Ashley-

Could Renate, Carrie, Adrienne, and I be invited to the EC call this afternoon and be on the invite list for future calls?

Thanks for your help!

John

Sent from my iPhone

Sent: 5/20/2020 1:38:09 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]
Subject: RE: Notes from the Vaccines WG meeting; Animal Model request; WG/SG member names to be made available

Hi Renate,

The new EC members are Gary Disbrow, BARDA and Peter Marks, FDA.

The

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Wednesday, May 20, 2020 9:01 AM
To: Melencio, Cheryl (FNIH) [T] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Notes from the Vaccines WG meeting; Animal Model request; WG/SG member names to be made available

Hi Cheryl:

These updates are made. Let me know if/when you hear from others.

Just a note that Francis asked that I add BMGF to the list of Non-Profit Leadership Organizations, which was added. Just wanted to make sure you, Abbey and Greta are aware. I also understand we're adding a few more folks to the EC. Ashley will provide me with those names and organizations and we'll update it today.

Thanks,
Renate

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Tuesday, May 19, 2020 3:38 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Notes from the Vaccines WG meeting; Animal Model request; WG/SG member names to be made available

See below – please use this:
Beth Bell, M.D.
Clinical Professor, Global Health
University of Washington

Cheryl Melencio
Administrative Manager, Research Partnerships

APAR0000017128

Foundation for the National Institutes of Health

b6

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From: Beth Bell [b6]

Sent: Tuesday, May 19, 2020 3:25 PM

To: Melencio, Cheryl (FNIH) [T]

b6

Subject: Fwd: Notes from the Vaccines WG meeting; Animal Model request; WG/SG member names to be made available

See below, as noted.

Sent from my iPad

Begin forwarded message:

From: Beth Bell

b6

Date: May 13, 2020 at 6:36:18 AM PDT

To: "Santos, Michael (FNIH) [T]"

b6

Subject: Re: Notes from the Vaccines WG meeting; Animal Model request; WG/SG member names to be made available

Michael,

I am not sure it's wise to describe me publicly as a former director of NCEZID at CDC. Maybe good for awareness of other WG members, but not appropriate publicly. So best to keep to my UW clinical appointment.

Many thanks for all the excellent work.

Beth Bell

Sent from my iPad

On May 12, 2020, at 3:26 PM, Santos, Michael (FNIH) [T] [b6] wrote:

Dear Vaccines Working Group members (and cc'ing others for awareness),

Thank you for your participation in yesterday's meeting. Attached are the summary notes from the meeting, plus an updated copy of the previous meeting's notes correcting two attendance omissions. Attached are also updated notes from the last meeting of the Protective Immune Responses Sub Group, with updates to the content

based on input from meeting participants. As always, please send any feedback on meeting notes and we will be happy to update and recirculate.

The Preclinical Working Group is collecting an animal model inventory. They have invited us to provide input on the **columns** of the attached spreadsheet, particularly the 'NHPs' tab: i.e., the request is for **what information they should collect in their inventory**, *not* to attempt to provide an inventory. We will ask the Protective Immune Responses Sub-Group to review, but are making the spreadsheet available to the whole group as anyone is invited to provide input by the end of this week. For awareness, the most recent Preclinical WG notes are also attached.

Finally, we have been informed that **the NIH intends to make the names of ACTIV Working Group and Sub-Group members publicly available** in the near future. Please contact us if you have any questions or concerns.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Saturday, May 9, 2020 10:16 PM
Subject: Review requested: Human Challenge Model draft; notes from Vaccines Sub-Groups, ACTIV Leadership Team, and Preclinical WG

Dear Vaccines Working Group members (and cc'ing others for awareness),

This note is an omnibus update for the Working Group: Sub-Group meeting notes, the human challenge model draft and agenda for the Working Group meeting, upcoming Vaccines Clinical Trial Sub-Group meetings and topics, and for awareness notes from the ACTIV Leadership Team meeting and Preclinical WG.

Sub-Group meeting notes

As a reminder, the Protective Immune Responses and Vaccine-associated Immune Enhancement Sub-Groups met since our last Working Group meeting (Thurs and Fri, respectively). Thank you to all who participated or sent input. **Attached are the notes and action items from each meeting.** The agendas and meeting materials and pre-reads are embedded in those documents. If anyone would like to be added to the lists for either Sub-Group, please let us know.

Review Controlled Human Infection Model outline in preparation for Monday's Working Group meeting

The main agenda item at the next Vaccines Working Group meeting, Monday, 12pm ET (9am PT / 6pm CEST), is a discussion of the Working Group's perspective on a CoV-2 controlled human infection model. Please review the attached outline to prepare for that discussion. If you cannot attend the meeting, feel free to send input via email that we can represent.

Vaccines Clinical Trial Sub-Group updates

Members of this Sub-Group are invited on Tuesday (11am ET) to join the Clinical Trial Capacity Working Group meeting, where Paula and Larry will share the plans of the Sub-Group and the CTC WG will share their activities and how they can work with us (e.g.,

inventory trial site capacity). **The Sub-Group meeting Wednesday (1pm ET) will focus on key protocol questions.**

ACTIV Leadership Team meeting notes

Last Wednesday, the ACTIV Leadership Team (the parent body above the Working Groups) met. Kathrin and Doug presented the progress and plans of the Working Group and answered questions. The meeting presentation and notes are attached. **Note: This is a good way to see a high-level summary of the activities of the other Working Groups, many of which are relevant to our work;** if you have specific questions, let us know and we can follow up.

Pre-clinical Working Group

Finally, as discussed last week we will continue to share notes from the Preclinical Working Group for awareness (attached zip file). **Note: a request to review the data collection fields for animal models will be coming to our group,** which we will circulate to the Protective Immune Responses and Vaccine-associated Immune Enhancement Sub-Groups.

As always, please don't hesitate to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health

b6 fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852
<image001.jpg>

<image002.jpg>

<image003.jpg>

<image004.jpg>

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<2020-05-11 Working Group meeting Summary Notes.docx>
<2020-05-05 Working Group meeting Summary Notes-updated.docx>
<2020-05-07 Protective Immune Responses Sub-Group meeting Notes-updated.docx>
<ACTIV PRECLINICAL_Animal Model Inventory_20200507.xlsx>
<2020-05-08_Preclinical_WG_Summary_D3.docx>

From: [REDACTED] b6
Sent: 5/20/2020 3:51:36 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboise!]
Subject: Re: is there a way...

Hi David,

I think you can use the draft language with links below. Cc'ing Renate.

Dear ACTIV leadership and working group members:

The NIH ACTIV webpage is now live: www.nih.gov/ACTIV. This is a soft launch, we are in the process of further refining the site and will include the list of participants for the working groups. Please stay tuned for updates — we anticipate a hard launch no later than Thursday, May 21st.

We've also launched the portal for submissions from potential partners and companies who are interested in submitting therapeutic and vaccine candidates for evaluation by our therapeutics clinical working group. The ACTIV webpage has a direct link to the portal "submit your ideas" and the portal is also featured on the NIH COVID-19 page: <https://www.nih.gov/health-information/coronavirus>

The direct link is:

Resources from NIH

- Scientists and Organizations can submit COVID-19 asset candidates to this portal

Thanks,

Ashley

Ashley Parker, Ph.D.
Special Assistant to Acting Chief of Staff to the NIH Director
Office of the Director | National Institutes of Health
Tel: [REDACTED] b6

On May 19, 2020, at 7:32 PM, Wholley, David (FNIH) [T] [REDACTED] b6 wrote:

...I could get a ready to send email from you on the new NIH resources, namely the submission portal and the NIH ACTIV website, that I could send tomorrow to all the Leadership Team and Working Group

folks? Just a couple of sentence on each (what they are) and the links? I just can't do that myself right now. Thank you.

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

Sent: 5/15/2020 7:57:44 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: DRAFT ACTIV Briefing with Moncef S. May 18 2020 051420 940PM.pptx

H

From: Santos, Michael (FNIH) [T] [b6]
Sent: Friday, May 15, 2020 3:50 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: DRAFT ACTIV Briefing with Moncef S. May 18 2020 051420 940PM.pptx

Hi Ashley,

As a preview, attached are the revised Vaccines slides.

Things have been pretty dynamic on the vaccines front over the last 36 hours. If it would be helpful to talk on the phone, I'd be happy to. You can reach me at: [b6] and I should be free any time except for a meeting at 4:30-5pm.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Friday, May 15, 2020 3:45 PM
To: Adam, Stacey (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: James, Stephanie (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>
Subject: RE: DRAFT ACTIV Briefing with Moncef S. May 18 2020 051420 940PM.pptx

The Vaccines slides are also updated on the I: drive master now.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, May 15, 2020 11:56 AM
To: Melencio, Cheryl (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
[b6]

Cc: James, Stephanie (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>
Subject: RE: DRAFT ACTIV Briefing with Moncef S. May 18 2020 051420 940PM.pptx

Hi Cheryl and David,

I have updated the slides for the TX-Clinical WG. Please let me know if they need further refinement.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Melencio, Cheryl (FNIH) [T] [b6]

Sent: Friday, May 15, 2020 11:44 AM

To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]

Cc: James, Stephanie (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>

Subject: RE: DRAFT ACTIV Briefing with Moncef S. May 18 2020 051420 940PM.pptx

I have put them on the I drive at: \\Research Partnerships\ACTIV Partnership\ACTIV Meetings\May 18 ACTIV Briefing - Moncef Slaoui\DRAFT ACTIV Briefing with Moncef S. May 18 2020 051420 940PM.pptx

I have created a folder under ACTIV Meetings\May 18 ACTIV Briefing -- Moncef Slaoui -- see link above

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

[b6]

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Wholley, David (FNIH) [T] [b6]

Sent: Friday, May 15, 2020 11:20 AM

To: Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]

Cc: James, Stephanie (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Melencio, Cheryl (FNIH) [T]

Subject: DRAFT ACTIV Briefing with Moncef S. May 18 2020 051420 940PM.pptx

Importance: High

Folks,

As I have mentioned there will be a meeting first thing Monday morning with Moncef Slaoui that will include Francis Collins, Tony Fauci, Janet Woodcock, Peter Marks and some others to bring Moncef up to speed on what ACTIV is all about and what progress we have made. Ashley Parker and I have been charged with getting a good draft of the slides in order by end of day today for Francis's review, though of course earlier is always better. I think the attached slides, which Ashley has put together from various slide presented to the Leadership Team and the NIH IC Directors, is a very good start. Per our daily update with Francis this morning, I believe we need the following updates however:

--Preclinical --Joe, just any new news that you think needs to be updated on the existing slides should be fine

--TX Clinical -- Stacey, we need the detailed slide(s) showing the process of how the therapeutics were/are going to be chosen which I know you were asked to start thinking about yesterday. If need be, one overview slide for the main part of the deck and a backup slide with more detail might be best, but I leave that to you.

Also, it would be good to update the slides on the protocols, especially plans for mAbs, with as much current detail as possible, with caveats as appropriate

--Clinical Trials Capacity -- Karen, please update the survey numbers and any further activities of the group. Highlighting progress/intentions on CROs probably not a bad idea

--Vaccines -- Mike, as you know, this is likely where Moncef is likely to spend a lot of his time given his background. FC particularly asked that we update this section with the current plans for the harmonized master protocols, including the intention of moving forward with the Moderna and Oxford/AZ vaccines as wave 1 of the strategy.

Cheryl, would you mind putting these into the I:drive somewhere where we can do central updates? I know it is a crazy day for all of us, but it would be good if I could see a more or less complete updated deck by 3:30 or so if possible, so I have time to review and share/discuss with Ashley. (Ashley if you have anything new in the meantime you can send it to me and Cheryl and we'll make sure it is put in the right place.)

Thanks, all--

David

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/15/2020 1:33:07 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: Canceled: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 5/18/2020 12:30:00 PM

End: 5/18/2020 1:00:00 PM

Show Time As: Free

Recurrence: Weekly
every Monday from 8:30 AM to 9:00 AM

Required Attendees: Wholley, David (FNIH) [T], Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E];

Optional Attendees: Austin, Christopher (NIH/NCATS) [E]; Freire, Maria (FNIH) [T]; Parker, Ashley (NIH/OD) [E]

Attendees: Wood, Gretchen (NIH/OD) [E], McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]

Cancelling this call due to ACTIV Briefing with Moncef Slaoui.

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Kolberg, Rebecca (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=30071513C5A8433A98883FD78D360A91-KOLBERGR]
Sent: 5/14/2020 3:08:26 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

And in my case today, recharged and ready to charge. Watch out!!

From: George, Jill (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:01 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Recharged and in charge!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:01 AM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

I finally got some rest last night and I have some fuel this morning! 😊

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:59 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Got it. Sounds like you were one step ahead of me!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:56 AM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Rebecca,

I've noted this change to Francis and Renate – please see attached. Apologies, I did not cc the entire group but will ensure we have the right naming of the WGs.

Thanks!
Ashley

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:48 AM

To: Burklow, John (NIH/OD) [E] [b6] Collins, Francis (NIH/OD) [E] [b6] Myles, Renate (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Fine, Amanda (NIH/OD) [E] [b6] Wojtowicz, Emma (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6] Schwetz, Tara (NIH/OD) [E] [b6] Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis & All,

Another picky editorial comment. On the second slide, we probably need to revise the name of the second working group to "Therapeutics Clinical Working Group." At least that was the name that FNIH asked us to use when Ashley and I were proofing your JAMA Viewpoint article yesterday evening. If that change is okay with everyone, I can have Jill George modify the slide and resend.

Rebecca

From: Burklow, John (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 10:39 AM

To: Collins, Francis (NIH/OD) [E] [b6] Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Fine, Amanda (NIH/OD) [E] [b6] Wojtowicz, Emma (NIH/OD) [E] [b6] Kolberg, Rebecca (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6] Schwetz, Tara (NIH/OD) [E] [b6] Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6] Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi, Francis—

We have a policy, worked out with OGC, where we don't include company logos on the NIH website. That said, FNIH could certainly post them. We'll come up with a graphic that includes the partners, etc., for the NIH page.

Thanks,

John

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 10:18 AM

To: Myles, Renate (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6] Freire, Maria (FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6] Fine, Amanda (NIH/OD) [E] [b6] Wojtowicz, Emma (NIH/OD) [E] [b6] Kolberg, Rebecca (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6] Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

How about these two?

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 8:03 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria

(FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]

Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,

Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne

(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)

[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]

[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis:

You mentioned that there are images in the presentations that we can use on the webpage, but those images seem very detailed and appear to contain confidential information to me. Would you let me know which particular image that you and David feel represents the overall program but doesn't give away too much information?

We're going to start building the page in draft today (not public).

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]

Sent: Wednesday, May 13, 2020 4:59 PM

To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria

(FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]

Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,

Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne

(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)

[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]

[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Thanks, all. This is great information. I can add the items from Francis and David to the strategic comms plan and will look for comments from Abbey on the webpage/plan.

Will FNIH reach out to the EC/WG members to ask permission for listing them on the website? We'd love to get this page up this week, if possible.

Best,
Renate

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Wednesday, May 13, 2020 4:38 PM

APAR0000017188

To: Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good points.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 4:19 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis: two other things that are possible and not already on your list below 1) the position paper from the ACTIV Vaccines WG on the issue of doing human challenge trials for Vaccines which I would hope would be ready for release by some time next week 2) a monoclonal antibodies master protocol, timing TBD (since we just received the charge this morning)
David

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 4:07 PM
To: Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi all,

I too want to say thanks to Renate for putting together this draft of the web page – it will be great to have something posted soon.

Building off of presentations to the Leadership Team/Exec Comm, we have a number of visuals that might be appropriate to include, and that would make the web site more pleasing to the eye.

I would be in favor of including the members of the working groups (it's a very impressive list) but only after asking their permission. It would also be good to designate the co-chairs of each of the Working Groups.

The Comms and Leg plan also looks good, though obviously there are uncertainties about the timing of various newsworthy events. In the not too distant future, I think we can imagine these developments:

- 1) Publication of the JAMA Viewpoint – Howard Bauchner has been moving this along at a very rapid pace, I wouldn't be surprised to see the publication emerge within the next week. Would that be a good moment to launch the web site?
- 2) Next week's planned summit, convened by ACTIV, on development of a master protocol(s) for monoclonal Abs – the meeting itself will be closed, but it might be possible to acknowledge that it's happening – as we did for the HEAL initiative a few times.
- 3) The launch of the anticoagulation four-arm trial, with leadership from NHLBI but under the ACTIV umbrella – I don't know exactly what the time table might be
- 4) The launch of the immunomodulator trial – which awaits working out the arrangements with the companies supplying the drugs, and then doing the match with the clinical trial networks that can make this work (through ACTT3)
- 5) The development and announcement of the harmonized master protocol for vaccines, with expectation that the first volunteers will be enrolled in the Ph II/III trials around July 1.

In the midst of all this, it looks like the US government is on the brink of announcing the joint HHS-DOD Manhattan Project 2, aka Operation Warp Speed, with Moncef Slaoui (former GSK) recruited to be the big kahuna, and a general from DoD as deputy. We will need to have materials ready to explain how that all fits with ACTIV. Jon Cohen's story has already confused the issue.

FC

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 3:24 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Renate,

I have looked at the NIH ACTIV webpage outline and communications and legislative strategy. Thank you for sending them.

The webpage outline is generally fine, Abbey will send you some specific comments. Please note that we have not made the names of the WG participants public in such a visible way. I have no concerns about this, although it appears that the NIH participants are more cautious about having their names out there.

On the communications and legislative strategy, it was very good to see that Carrie's shop is featured prominently. They do an outstanding job at putting together the summaries and technical descriptions of the activities of the PPPs, as they have done in AMP and HEAL.

You have identified some portions for FNIH input. Abbey will reach out directly to you to clarify exactly what you anticipate to be the FNIH role in this.

Thanks, Maria

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Tuesday, May 12, 2020 2:43 PM

To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];

Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6];

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];

Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6];

Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,

Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne

(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)

[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]

[b6]

Subject: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good afternoon:

In the interest of time, I wanted to share the attached two items for both NIH and FNIH leadership review. Attached are:

1) Draft web content for a proposed NIH ACTIV web page:

- Currently, the content is based primarily on publicly available information (mostly pulled from the release).
- The only new content is the listing of the Executive Committee and Working Group members.
- Having an ACTIV webpage will provide interested stakeholders with a central resource for ACTIV information, including releases, scientific papers, blogs, etc.; will point people to the scientific portal for submitting assets; and would allow us to provide status updates, as appropriate and as desired, on ACTIV developments.
- This page can be expanded when we are ready to make more information public.

2) Draft ACTIV Communication and Legislative Strategy:

- The strategy includes proposed tactics that could be developed in the near term, as well as longer lead items that we can prepare for now as we consider appropriate timing.

If it's helpful, we'd be happy to participate in a call to talk through these recommendations with you. We look forward to your feedback.

Best,
Renate

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institute of Health
[b6]

Sent: 5/14/2020 1:30:36 AM
To: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Very good points. Should we make this decision now – I think we would need to ask

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 9:24 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Just curious. If ACTIV has a Therapeutics Clinical Working Group, why is isn't the Vaccines Working Group called the Vaccines Clinical Working Group for parallel nomenclature? Or, alternatively, why not refer to the Therapeutics Clinical Working Group as the Therapeutics Working Group?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 9:19 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

The names of the working groups have varied since the initiation – here is how they are referred to most recently.

- Preclinical Working Group
- Therapeutics Clinical Working Group
- Clinical Trial Capacity Working Group
- Vaccines Working Group

Thanks for catching that!

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 9:00 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

What are the official names of the Working Groups? Do you or David Wholley have a list? The text of this article says that the Preclinical Working Group covers both therapeutics and vaccines, so we can't really call it Preclinical Therapeutics Working Group in either the text or the figure.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 8:57 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

This explains to renaming of the working groups in the figure. As Rebecca has indicated we will need to be consistent.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 8:15 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: FW: JAMA Viewpoint on ACTIV: please review

From: Howard Bauchner [b6]
Sent: Wednesday, May 13, 2020 5:25 PM
To: Stacy Christiansen [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Karen Bucher [b6]
Subject: Re: JAMA Viewpoint on ACTIV: please review

Francis

Stacy is Managing Editor of JAMA and is working every day to get our content out. She leads our manuscript editing group.

Karen is head of graphics and redid your figure (everything at JAMA is redrawn).

Please let Karen know if you prefer a different look.

Comments on the text go to Stacy.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my [chats with authors](#)

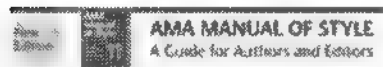
From: Stacy Christiansen [b6]
Date: Wednesday, May 13, 2020 at 4:22 PM
To: Francis Collins [b6]
Cc: Howard Bauchner [b6]; Karen Bucher [b6]
Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,
Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

Thank you so much!
Best, Stacy
Stacy L. Christiansen, MA
Managing Editor, *JAMA*
Chair, *AMA Manual of Style*



Sent: 5/14/2020 1:05:44 AM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

-----Original Message-----

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 7:50 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E]
CC: George, Jill (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

Please resend; the file was corrupted.

On 5/13/20, 7:10 PM, "Parker, Ashley (NIH/OD) [E]" [b6] wrote:

Hi Francis,

Please see the slide set with additions from today's vaccine working group meeting (with input from Mike Santos, please see notes). With many thanks to Tara and Jill, please also see the RADx and COVID portal slides for possible inclusion.

Thanks,
Ashley

I-----Original Message-----

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 3:33 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
CC: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Francis,

We've asked for the slides NIAID presented on the draft plan to the vaccine working today and will provide a single summary slide.

Thanks,
Ashley

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 1:28 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
CC: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Looks good, though I have done some trimming and re-arranging.

I want to add a slide to summarize what the Vaccines WG came up with today on the harmonized master protocol -- will there be a shared DSMB, shared agreement on endpoints, lab assays, etc. Can that be provided by the end of the day?

FC

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 11:23 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Francis,

Please see the attached revised set for tomorrow's ICD meeting based on your notes below and discussions at the ACTIV EC meeting this morning. There are 9 core presentation slides and I've moved the challenges/recommended actions (slides 10-11) to the end for discussion with the group.

As mentioned on our call yesterday, I think Jim would like to briefly discuss the NHP strategy/use of resources (slide 5) if time permits -- looping in Jim to confirm.

standing by if anything else is needed.

Thanks,
Ashley

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 7:18 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
George, Jill (NIH/OD) [E] [b6]
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

Hi Francis,

Great plan - we will adjust accordingly and standby for additional edits that may come out of the executive committee meeting.

Thanks,
Ashley

> On May 13, 2020, at 7:03 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

>
> Hi Ashley,

> Thanks for putting this slide set together. I'd like to see what happens in the Exec Comm/WG meeting this morning, and then we can finalize. I will want to move many of the slides to back up -- as we only have a half hour for the discussion and the presentation part shouldn't be more than 10 minutes - the main goal is to inspire discussion. You can take out the discussion place holder slides -- I think I will try to go through the whole presentation before opening it up to questions, or we might not get to the vaccines.

> Francis

> -----Original Message-----

> From: Parker, Ashley (NIH/OD) [E] [b6]
> Sent: Tuesday, May 12, 2020 7:04 PM
> To: Collins, Francis (NIH/OD) [E] [b6]
> Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; George, Jill (NIH/OD) [E]
> <georgejil@od.nih.gov>
> Subject: RE: Materials: ICD Meeting Committee 5/14/2020

> Hi Francis,

> Please see attached draft ACTIV slides for the ICD meeting on Thursday. With thanks to Jill for formatting.

> I've included place holder slides for discussion in between the working group topics in case you want to stop and take questions/discuss -- we can delete these if you prefer to hold discussions for the end.

> Thank you,
> Ashley

> -----Original Message-----

> From: Wholley, David (FNIH) [T] [b6]
> Sent: Tuesday, May 12, 2020 7:14 AM

> To: Parker, Ashley (NIH/OD) [E] [b6]; Collins,
> Francis (NIH/OD) [E] [b6]
> Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
> Subject: RE: Materials: ICD Meeting Committee 5/14/2020
>
> Send them the Science article too
>
> -----Original Message-----
> From: Parker, Ashley (NIH/OD) [E] [b6]
> Sent: Tuesday, May 12, 2020 6:39 AM
> To: Collins, Francis (NIH/OD) [E] [b6]
> Cc: Wholley, David (FNIH) [T] [b6]; TABAK, Lawrence
> (NIH/OD) [E] [b6]
> Subject: Re: Materials: ICD Meeting Committee 5/14/2020
>
> Hi Francis,
>
> Happy to work with David and his team to prepare slides. Is the plan to share any updates since
the ACTIV leadership meeting last Wednesday? Honestly, not sure if there's a lot to report on the
working groups at the moment however I defer to David.
>
> Are there other items, anything else specifically you would like to discuss with the ICDs about
ACTIV? Mention of JAMA article but this doesn't need a slide, right?
>
> Happy to help.
>
> Thanks,
> Ashley
>
>
>> On May 12, 2020, at 6:27 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:
>>
>> Hi Ashley and David,
>>
>> I'll need some help preparing a presentation on ACTIV for ICs on Thursday. Larry, should there
also be a RADx update? Are you hearing from ICs about this?
>>
>> FC
>>
>> From: Tabak, Lawrence (NIH/OD) [E] [b6]
>> Sent: Monday, May 11, 2020 10:22 PM
>> To: ICDDIR-L@LIST.NIH.GOV
>> Cc: IC Directors Meeting <ICDirectorsMeeting@od.nih.gov>
>> Subject: Materials: ICD Meeting Committee 5/14/2020
>>
>> Colleagues,
>>
>> We will have a IC Directors meeting Thursday, May 14, 8:30 AM to 10:00 AM by WebEx.
>>
>> Materials are attached.
>>
>> * Agenda
>> * AoU Researcher Workbench
>>
>> Materials are also posted to the ICD SharePoint site:
>> <https://sps.od.nih.gov/ICdirector/default.aspx>
>>
>> Thanks,
>> Larry
>>
>> ---
>> JOIN WEBEX MEETING
>> <https://nih.webex.com/nih> [b6]
>> a Meeting number (access code): [b6] Meeting password:
>> [b6]
>>
>>
>> * When choosing your audio connection, select either the Call Me, I Will Call In*, Call Using
Computer (Desktop), or Use Internet for audio (Mobile) feature to ensure your name appears in the
participant list.
>> * If you chose the I Will Call In dial-in option, please be sure to enter your attendee ID
number that will be displayed once you are logged in from your computer in an effort to identify each
participant.
>> * Phone dial-in should only be used as a last resort means if the WebEx site, desktop or mobile
app cannot be utilized. If using a phone, when your time to speak is open, use *6 to unmute yourself. If
you use this method please email Jordan Gladman with your phone number.
>>
>> JOIN BY PHONE

>> [b6] Call-in number (US/Canada)
>>
>> Access code: [b6]
>>
>>
>> <2020-05-14_IC Directors Agenda.docx> <IC Directors Presentation
>> 05.14.20 - Long - Read-Only.pptx> <IC Directors Presentation
>> 05.14.20 - short[1] - Read-Only.pptx>

Sent: 2/10/2021 2:38:27 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponefm]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wann, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35a10ade04db43c997fbbc28531571fc-wanneg]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Thompson, Katherine (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f2c78f864ae43558adb82dc6b9a4d71-thompsonkap]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: PLEASE REVIEW THESE DOCUMENTS: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page
Attachments: RE: FOR YOUR REVIEW: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Attached are the edits/comments I shared previously and it seems they were not included.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Wednesday, February 10, 2021 9:28 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: RE: PLEASE REVIEW THESE DOCUMENTS: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Wonderful; thank you, David. I agree; 14 is a lot! I will check with Cliff on this description. And we can make the banner on the ACTIV-associated trials a different color to distinguish it from the ACTIV trials.

Francis: let me know if you have any additional input.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, February 10, 2021 9:20 AM

To: Myles, Renate (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: PLEASE REVIEW THESE DOCUMENTS: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Hi Renate:

Great work, these look fine to me. My only comment is that you may want more of a separator or something between the ACTIV and the ACTIV-associated trials so there is a clear distinction between them. The revised definition of ACTIV-associated sounds good, but as these are NIAID-run studies you might just want to double-check the definition with Cliff Lane.

So for ACTIV alone I count that we are testing 13 distinct treatments involving 14 drugs (the Bria cocktail has two agents). Not bad.

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Wednesday, February 10, 2021 7:50 AM

To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: PLEASE REVIEW THESE DOCUMENTS: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Hi all:

Please review these two documents. Stacey provided a correction on the quick view table.

A few notes:

- 1) I need your input on how best to describe Active-associated trials. I don't think the current description (NIH-funded, randomized, placebo-controlled clinical trials that are at Phase 2 or later) sufficiently distinguishes these trials from other trials not listed. Would it be appropriate to add: that are prioritized by the COVID-19 Vaccines/Therapeutics Operation (formerly OWS)?
- 2) These two items were reviewed by NIAID, NCATS, and NHLBI.
- 3) We point to the ACTIV protocols on this therapeutics page, but the ICs have indicated that the protocols for ACTIV-associated trials are not public and they are not planning on making them public.

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]

Sent: Tuesday, February 9, 2021 8:13 PM

To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey

(FNIH) [T] [b6] Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T]
[b6] Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: FOR YOUR REVIEW: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Hi all:

Attached for your final review are the Quick View Table and the ACTIV-Associated content for the ACTIV Therapeutics page. We added AZD742 to the ACTIV-3 list since that is now public.

I do feel like we need more info to explain why these trials are ACTIV-Associated. As currently defined, it seems many other trials could be included. See my comment in the second document attached.

Once I get your input and final okay, we will proceed with posting these on the ACTIV therapeutics page.

Many thanks,
Renate

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Monday, February 8, 2021 9:02 AM

To: Wholley, David (FNIH) [T] [b6] Collins, Francis (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6] Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]

Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T] [b6]

[b6] Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6] Menetski, Joseph (FNIH) [T] [b6]

Subject: Re: FOR YOUR REVIEW: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Thank you, David.

Ashley: regarding your point about CSS1 and CSS4, since these aren't NIH funded, which is a criteria that you defined, I plan to exclude those.

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health

[b6]

From: Wholley, David (FNIH) [T] [b6]

Sent: Monday, February 8, 2021 7:33 AM

To: Myles, Renate (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]

Cc: Burklow, John (NIH/OD) [E]; Fine, Amanda (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]; Brodd, Lauren (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wann, Ellen (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]; Thompson, Katherine (FNIH) [T];

Adam, Stacey (FNIH) [T]; Menetski, Joseph (FNIH) [T]

Subject: RE: FOR YOUR REVIEW: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Renate:

The table left out one of the ACTIV-1 agents (cenicriviroc). The corrected table is attached. Thanks, David

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Sunday, February 7, 2021 3:14 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: FOR YOUR REVIEW: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Hi all:

Attached for your review are:

1. Quick View Table of all therapeutics in ACTIV, including ACTIV-like trials, that will be added to the ACTIV Therapeutics page.
 1. Note that this table does not include the new agents coming into ACTIV-2 and ACTIV-3. We will add those once they are announced. Statements are ready; NIAID is waiting on enrollment.
 2. Also, I am waiting to hear from NIAID if CSSC-004 is NIH funded (I do not believe it is).
2. ACTIV-like trial information to add to the ACTIV Therapeutics page similar to other listings on the page.

I will also run these by NIAID, NHLBI, and NCATS for review.

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Sunday, February 7, 2021 8:09 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: Re: Two Items for Your Input

Thanks, David. I'll send the content around for review as soon as it's finalized.

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health

[b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Sunday, February 7, 2021 6:54:31 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey

(FNIH) [T] <[b6]>; Thompson, Katherine (FNIH) [T] <[b6]>; Adam, Stacey (FNIH) [T] <[b6]>; Menetski, Joseph (FNIH) [T] <[b6]>

Subject: RE: Two Items for Your Input

Hi Renate:

Thanks for your diligence on this. These trials are on Combat COVID because they are HHS sponsored/affiliated. If we want to list only NIH trials, then they should be removed from the list. Wasn't quite clear to us when we had Deloitte put this together exactly what the criteria were to be. Thanks for your diligence on this.

From: Myles, Renate (NIH/OD) [E] <[b6]>

Sent: Friday, February 5, 2021 11:53 PM

To: Wholley, David (FNIH) [T] <[b6]>; Collins, Francis (NIH/OD) [E] <[b6]>; Parker, Ashley (NIH/OD) [E] <[b6]>; Melencio, Cheryl (FNIH) [T] <[b6]>

Cc: Burklow, John (NIH/OD) [E] <[b6]>; Fine, Amanda (NIH/OD) [E] <[b6]>; Wojtowicz, Emma (NIH/OD) [E] <[b6]>; Brodd, Lauren (NIH/OD) [E] <[b6]>; Gadbois, Ellen (NIH/OD) [E] <[b6]>; Wann, Ellen (NIH/OD) [E] <[b6]>; Meltzer, Abbey (FNIH) [T] <[b6]>; Thompson, Katherine (FNIH) [T] <[b6]>; Adam, Stacey (FNIH) [T] <[b6]>; Menetski, Joseph (FNIH) [T] <[b6]>

Subject: RE: Two Items for Your Input

Hi David:

It does not appear that NIH is funding (or is any way involved in) these three trials on the list, so I will not include them unless I hear otherwise:

1. CSSC-001: <https://clinicaltrials.gov/ct2/show/NCT04323800>
2. Storm Chaser: <https://clinicaltrials.gov/ct2/show/NCT04625972>
3. iLeukPulm: <https://clinicaltrials.gov/ct2/show/NCT04411680>

It's unclear if NIAID is funding the one below or is just a collaborator; please let me know:

1. CSSC-004: <https://clinicaltrials.gov/ct2/show/NCT04373460>

Thanks,
Renate

From: Wholley, David (FNIH) [T] <[b6]>

Sent: Friday, February 5, 2021 11:20 PM

To: Collins, Francis (NIH/OD) [E] <[b6]>; Myles, Renate (NIH/OD) [E] <[b6]>; Parker, Ashley (NIH/OD) [E] <[b6]>; Melencio, Cheryl (FNIH) [T] <[b6]>

Cc: Burklow, John (NIH/OD) [E] <[b6]>; Fine, Amanda (NIH/OD) [E] <[b6]>; Wojtowicz, Emma (NIH/OD) [E] <[b6]>; Brodd, Lauren (NIH/OD) [E] <[b6]>; Gadbois, Ellen (NIH/OD) [E] <[b6]>; Wann, Ellen (NIH/OD) [E] <[b6]>; Meltzer, Abbey (FNIH) [T] <[b6]>; Thompson, Katherine (FNIH) [T] <[b6]>; Adam, Stacey (FNIH) [T] <[b6]>; Menetski, Joseph (FNIH) [T] <[b6]>

Subject: RE: Two Items for Your Input

Then all the trials on the list are fine.

From: Collins, Francis (NIH/OD) [E] <[b6]>

Sent: Friday, February 5, 2021 6:30 PM

To: Myles, Renate (NIH/OD) [E] <[b6]>; Wholley, David (FNIH) [T] <[b6]>; Parker, Ashley (NIH/OD) [E] <[b6]>; Melencio, Cheryl (FNIH) [T] <[b6]>

Cc: Burklow, John (NIH/OD) [E] <[b6]>; Fine, Amanda (NIH/OD) [E] <[b6]>

Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6] Meltzer, Abbey
(FNIH) [T] [b6] Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T]
[b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: RE: Two Items for Your Input

Why does that exclude CP?

I don't think the master protocol is essential to be an ACTIV-associated trial. But it needs to be a well-powered placebo-controlled randomized trial with well defined endpoints and a DSMB.

FC

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, February 5, 2021 6:24 PM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio,
Cheryl (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];
Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6] Meltzer, Abbey
(FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T]
[b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: RE: Two Items for Your Input

Adding Francis.

Francis: per our discussion, I captured ACTIV-associated trials as NIH-sponsored, randomized, placebo-controlled trial for agents in Phase 2 or higher using a master protocol. But that excludes the CP trials.

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, February 5, 2021 5:58 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];
Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Gadbois, Ellen (NIH/OD) [E] [b6] Wann, Ellen (NIH/OD) [E] [b6] Meltzer, Abbey
(FNIH) [T] [b6] Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T]
[b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: RE: Two Items for Your Input

Renate:

StormChaser is the prophylaxis study of AZ's nAb cocktail. They are cross-sharing sites with ACTIV-2 and using the NIH Combat COVID website—believe it is funded by OWS. So no, according to Francis's stricter definition it is not ACTIV-associated and comes off the list, as do the CP trials (which may have been referred to in the past as ACTIV-associated, I don't remember). We're having a look at what else would come off in that case, and will get back to you.
David

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, February 5, 2021 5:43 PM
To: Wholley, David (FNIH) [T] [b6] Parker, Ashley (NIH/OD) [E] [b6]; Melencio,

Cheryl (FNIH) [T] <[b6]>
Cc: Burklow, John (NIH/OD) [E] <[b6]>; Fine, Amanda (NIH/OD) [E] <[b6]>;
Wojtowicz, Emma (NIH/OD) [E] <[b6]>; Brodd, Lauren (NIH/OD) [E] <[b6]>;
Gadbois, Ellen (NIH/OD) [E] <[b6]>; Wann, Ellen (NIH/OD) [E] <[b6]>; Meltzer, Abbey
(FNIH) [T] <[b6]>; Thompson, Katherine (FNIH) [T] <[b6]>; Adam, Stacey (FNIH) [T]
<[b6]>; Menetski, Joseph (FNIH) [T] <[b6]>

Subject: RE: Two Items for Your Input

Hi David and Ashley:

John and I were discussing the table with Francis and none of us knew were familiar with the AZD7442 Storm Chaser protocol. The CT.gov record doesn't list NIH: <https://clinicaltrials.gov/ct2/show/NCT04625972> Thanks for any additional info you can provide on it.

Also, Francis indicated to be ACTIV-associated the trial must use a master protocol for a randomized, placebo-controlled trial for agents in Phase 2 or higher. Is that how you see it as well?

Best,
Renate

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Friday, February 5, 2021 9:39 AM
To: Parker, Ashley (NIH/OD) [E] <[b6]>; Myles, Renate (NIH/OD) [E] <[b6]>;
Melencio, Cheryl (FNIH) [T] <[b6]>
Cc: Burklow, John (NIH/OD) [E] <[b6]>; Fine, Amanda (NIH/OD) [E] <[b6]>;
Wojtowicz, Emma (NIH/OD) [E] <[b6]>; Brodd, Lauren (NIH/OD) [E] <[b6]>;
Gadbois, Ellen (NIH/OD) [E] <[b6]>; Wann, Ellen (NIH/OD) [E] <[b6]>; Meltzer, Abbey
(FNIH) [T] <[b6]>; Thompson, Katherine (FNIH) [T] <[b6]>; Adam, Stacey (FNIH) [T]
<[b6]>; Menetski, Joseph (FNIH) [T] <[b6]>
Subject: RE: Two Items for Your Input

That seems fine to me.

From: Parker, Ashley (NIH/OD) [E] <[b6]>
Sent: Friday, February 5, 2021 9:16 AM
To: Wholley, David (FNIH) [T] <[b6]>; Myles, Renate (NIH/OD) [E] <[b6]>; Melencio,
Cheryl (FNIH) [T] <[b6]>
Cc: Burklow, John (NIH/OD) [E] <[b6]>; Fine, Amanda (NIH/OD) [E] <[b6]>;
Wojtowicz, Emma (NIH/OD) [E] <[b6]>; Brodd, Lauren (NIH/OD) [E] <[b6]>;
Gadbois, Ellen (NIH/OD) [E] <[b6]>; Wann, Ellen (NIH/OD) [E] <[b6]>; Meltzer, Abbey
(FNIH) [T] <[b6]>; Thompson, Katherine (FNIH) [T] <[b6]>
Subject: RE: Two Items for Your Input

Hi David and Renate,

We've previously used the definitions below to distinguish ACTIV trials from ACTIV-associated trials – feel free to edit to your preference.

ACTIV trials = NIH, other federal agencies and ~20 industry and non-profit partners

ACTIV associated trials = NIH sponsored trials with one or more industry partners

Thanks,

Ashley

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Thursday, February 4, 2021 8:39 PM
To: Myles, Renate (NIH/OD) [E] <[b6]>; Melencio, Cheryl (FNIH) [T] <[b6]>
Cc: Burklow, John (NIH/OD) [E] <[b6]>; Fine, Amanda (NIH/OD) [E] <[b6]>
Wojtowicz, Emma (NIH/OD) [E] <[b6]>; Parker, Ashley (NIH/OD) [E] <[b6]>;
Brodd, Lauren (NIH/OD) [E] <[b6]>; Gadbois, Ellen (NIH/OD) [E] <[b6]>; Wann, Ellen
(NIH/OD) [E] <[b6]>; Meltzer, Abbey (FNIH) [T] <[b6]>; Thompson, Katherine (FNIH) [T]
<[b6]>
Subject: RE: Two Items for Your Input

Great. Happy to have my team review either or both.

From: Myles, Renate (NIH/OD) [E] <[b6]>
Sent: Thursday, February 4, 2021 8:37 PM
To: Wholley, David (FNIH) [T] <[b6]>; Melencio, Cheryl (FNIH) [T] <[b6]>
Cc: Burklow, John (NIH/OD) [E] <[b6]>; Fine, Amanda (NIH/OD) [E] <[b6]>;
Wojtowicz, Emma (NIH/OD) [E] <[b6]>; Parker, Ashley (NIH/OD) [E] <[b6]>;
Brodd, Lauren (NIH/OD) [E] <[b6]>; Gadbois, Ellen (NIH/OD) [E] <[b6]>; Wann, Ellen
(NIH/OD) [E] <[b6]>; Meltzer, Abbey (FNIH) [T] <[b6]>; Thompson, Katherine (FNIH) [T]
<[b6]>
Subject: Re: Two Items for Your Input

Thanks, David. We can create the ACTIV table and can coordinate with our NIH colleagues on how best to describe ACTIV-like.

Thanks,
Renate

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health

[b6]

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Thursday, February 4, 2021 8:22:15 PM
To: Myles, Renate (NIH/OD) [E] <[b6]>; Melencio, Cheryl (FNIH) [T] <[b6]>
Cc: Burklow, John (NIH/OD) [E] <[b6]>; Fine, Amanda (NIH/OD) [E] <[b6]>
Wojtowicz, Emma (NIH/OD) [E] <[b6]>; Parker, Ashley (NIH/OD) [E] <[b6]>;
Brodd, Lauren (NIH/OD) [E] <[b6]>; Gadbois, Ellen (NIH/OD) [E] <[b6]>; Wann, Ellen
(NIH/OD) [E] <[b6]>; Meltzer, Abbey (FNIH) [T] <[b6]>; Thompson, Katherine (FNIH) [T]
<[b6]>
Subject: RE: Two Items for Your Input

Renate: answers are as follows—

1. No, we have no current plans to turn the spreadsheets into a graphic table. You can do this, or we'd be happy to ask our Deloitte colleagues to do so. Please let me know. We will be happy to reach out to NIH colleagues as to how to describe the ACTIV-associated activities for the NIH ACTIV webpage, or better yet to point you to the right people at NIH to seek the information needed.

2. As for the AMP diagram, let me please circulate it to my team so we get you the exact timelines and funding numbers, at least as we see them. I see Ellens Wann and Gadbois are already copied on this note, so I will copy them on that reply so they can confirm the accuracy of our input.

Thanks, David

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Thursday, February 4, 2021 12:58 PM

To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];

Wojtowicz, Emma (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6];

Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen

(NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T]

[b6]

Subject: Two Items for Your Input

Hi David:

I hope this note finds you well. We need your input on two items, one ACTIV related and one AMP related.

1. Francis shared the excel sheet that lists the public ACTIV and ACTIV-like therapeutics in a simple table. Is FNIH developing a graphic table that we can post to the ACTIV page? We will need to also create an ACTIV-like item for the [ACTIV Therapeutics page](#), similar to the other ACTIV therapeutic projects. We would welcome your input on how best to describe ACTIV-like projects. As you may know, we have two national stories in the works on this, a 60 Minutes piece, which Francis will be filmed for next week, and a New Yorker piece, which has been in the works for several months and is expected to publish this month (FC will have his second interview the week of Feb. 15). We'd love to be able to point both outlets to the public graph ahead of the interviews. I'm sure you also saw the [Time profile on Francis](#), which includes a lot of information about ACTIV. We're hoping he makes the cover.
1. We are in the process of preparing the rollout for the AMP AD 2.0 announcement. We discussed the [current representation of the budget on the main AMP page](#) with Ellen Gadbois and Ellen Wann and thought that an updated version of the attached graph could replace the current budget table. We would only include current projects and AMP AD 2.0. I do think there are a few things that need to be fixed in the graph, such as showing when AD 1.0 ends, which I believe overlaps with when AD 2.0 begins. We would post the graph when we announce AD 2.0, currently scheduled for Feb. 18. Let us know if you are okay with this approach.

Thanks for your input.

Best,
Renate

Renate Myles, MBA

Deputy Director for Public Affairs

Office of Communications and Public Liaison

National Institute of Health

[b6]

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

Sent: 2/8/2021 8:39:18 AM

To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wann, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35a10ade04db43c997fbbc28531571fc-wanneg]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Thompson, Katherine (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f2c78f864ae43558adb82dc6b9a4d71-thompsonkap]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]

Subject: RE: FOR YOUR REVIEW: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Hi Renate et al.,

Looks great! Minor comments below:

- Quick view table: should we include both classes for the remdesivir + IVIG study (ITAC trial)? Defer to the experts – Antiviral/Polyclonal antibody or Antiviral/Immune Modulator?

Gilead & Other	Remdesivir and Hyperimmune Intravenous Immunoglobulin (hIVIG)	Antiviral	Intravenous	N/A	Q3 2021
----------------	---	-----------	-------------	-----	---------

- DOD is funding both CP trials led by JHU—CSSC-001: <https://clinicaltrials.gov/ct2/show/NCT04323800> and CSSC-004: <https://clinicaltrials.gov/ct2/show/NCT04373460>. NCATS has worked closely with the PI David Sullivan, who to my understanding drafted protocols for both JHU trials and I think NIAID is a collaborator for CSSC-004 but defer to NIAID for the details. I would also mention we've (OD) worked with HHS to provide DOD with necessary testing kits and machines to accelerate their outpatient CP trials (CSSC-004) and NHLBI has collaborated with this trial on harmonizing endpoints.

- 2nd attachment: although both “like” and “associated” have both floated around, I think we previously settled on “ACTIV-Associated trials” to describe those that fall under the umbrella of ACTIV but defer to others.
 - Subhead: ACTIVE-like trials are NIH-funded, randomized, placebo-controlled clinical trials with one or more industry partners? that are at Phase 2 or later.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Sunday, February 7, 2021 3:14 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: FOR YOUR REVIEW: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Hi all:

Attached for your review are:

- 1) Quick View Table of all therapeutics in ACTIV, including ACTIV-like trials, that will be added to the ACTIV Therapeutics page.
 - a. Note that this table does not include the new agents coming into ACTIV-2 and ACTIV-3. We will add those once they are announced. Statements are ready; NIAID is waiting on enrollment.
 - b. Also, I am waiting to hear from NIAID if CSSC-004 is NIH funded (I do not believe it is).
- 2) ACTIV-like trial information to add to the ACTIV Therapeutics page similar to other listings on the page.

I will also run these by NIAID, NHLBI, and NCATS for review.

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Sunday, February 7, 2021 8:09 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: Re: Two Items for Your Input

Thanks, David. I'll send the content around for review as soon as it's finalized.

Renate Myles
Deputy Director for Public Affairs

Office of Communications and Public Liaison
National Institutes of Health

b6

From: Wholley, David (FNIH) [T] b6
Sent: Sunday, February 7, 2021 6:54:31 AM
To: Myles, Renate (NIH/OD) [E] b6; Collins, Francis (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6; Melencio, Cheryl (FNIH) [T] b6
Cc: Burklow, John (NIH/OD) [E] b6; Fine, Amanda (NIH/OD) [E] b6; Wojtowicz, Emma (NIH/OD) [E] b6; Brodd, Lauren (NIH/OD) [E] b6; Gadbois, Ellen (NIH/OD) [E] b6; Wann, Ellen (NIH/OD) [E] b6; Meltzer, Abbey (FNIH) [T] b6; Thompson, Katherine (FNIH) [T] b6; Adam, Stacey (FNIH) [T] b6; Menetski, Joseph (FNIH) [T] b6
Subject: RE: Two Items for Your Input

Hi Renate:

Thanks for your diligence on this. These trials are on Combat COVID because they are HHS sponsored/affiliated. If we want to list only NIH trials, then they should be removed from the list. Wasn't quite clear to us when we had Deloitte put this together exactly what the criteria were to be. Thanks for your diligence on this.

From: Myles, Renate (NIH/OD) [E] b6
Sent: Friday, February 5, 2021 11:53 PM
To: Wholley, David (FNIH) [T] b6; Collins, Francis (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6; Melencio, Cheryl (FNIH) [T] b6
Cc: Burklow, John (NIH/OD) [E] b6; Fine, Amanda (NIH/OD) [E] b6; Wojtowicz, Emma (NIH/OD) [E] b6; Brodd, Lauren (NIH/OD) [E] b6; Gadbois, Ellen (NIH/OD) [E] b6; Wann, Ellen (NIH/OD) [E] b6; Meltzer, Abbey (FNIH) [T] b6; Thompson, Katherine (FNIH) [T] b6; Adam, Stacey (FNIH) [T] b6; Menetski, Joseph (FNIH) [T] b6
Subject: RE: Two Items for Your Input

Hi David:

It does not appear that NIH is funding (or is any way involved in) these three trials on the list, so I will not include them unless I hear otherwise:

- CSSC-001: <https://clinicaltrials.gov/ct2/show/NCT04323800>
- Storm Chaser: <https://clinicaltrials.gov/ct2/show/NCT04625972>
- iLeukPulm: <https://clinicaltrials.gov/ct2/show/NCT04411680>

It's unclear if NIAID is funding the one below or is just a collaborator; please let me know:

- CSSC-004: <https://clinicaltrials.gov/ct2/show/NCT04373460>

Thanks,
Renate

From: Wholley, David (FNIH) [T] b6
Sent: Friday, February 5, 2021 11:20 PM
To: Collins, Francis (NIH/OD) [E] b6; Myles, Renate (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6; Melencio, Cheryl (FNIH) [T] b6
Cc: Burklow, John (NIH/OD) [E] b6; Fine, Amanda (NIH/OD) [E] b6; Wojtowicz, Emma (NIH/OD) [E] b6; Brodd, Lauren (NIH/OD) [E] b6; Gadbois, Ellen (NIH/OD) [E] b6; Wann, Ellen (NIH/OD) [E] b6; Meltzer, Abbey (FNIH) [T] b6; Thompson, Katherine (FNIH) [T] b6; Adam, Stacey (FNIH) [T] b6

[b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Then all the trials on the list are fine.

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Friday, February 5, 2021 6:30 PM

To: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Parker, Ashley

(NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]

Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey

(FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T]

[b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Why does that exclude CP?

I don't think the master protocol is essential to be an ACTIV-associated trial. But it needs to be a well-powered placebo-controlled randomized trial with well defined endpoints and a DSMB.

FC

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Friday, February 5, 2021 6:24 PM

To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio,

Cheryl (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]

Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey

(FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T]

[b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Adding Francis.

Francis: per our discussion, I captured ACTIV-associated trials as NIH-sponsored, randomized, placebo-controlled trial for agents in Phase 2 or higher using a master protocol. But that excludes the CP trials.

From: Wholley, David (FNIH) [T] [b6]

Sent: Friday, February 5, 2021 5:58 PM

To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]

Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]

Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey

(FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T]

[b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Renate:

StormChaser is the prophylaxis study of AZ's nAb cocktail. They are cross-sharing sites with ACTIV-2 and using the NIH Combat COVID website—believe it is funded by OWS. So no, according to Francis's stricter definition it is not ACTIV-associated and comes off the list, as do the CP trials (which may have been referred to in the past as ACTIV-associated, I don't remember). We're having a look at what else would come off in that case, and will get back to you.

David

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Friday, February 5, 2021 5:43 PM

To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]

Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey

(FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T]

[b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Hi David and Ashley:

John and I were discussing the table with Francis and none of us knew were familiar with the AZD7442 Storm Chaser protocol. The CT.gov record doesn't list NIH: <https://clinicaltrials.gov/ct2/show/NCT04625972>. Thanks for any additional info you can provide on it.

Also, Francis indicated to be ACTIV-associated the trial must use a master protocol for a randomized, placebo-controlled trial for agents in Phase 2 or higher. Is that how you see it as well?

Best,
Renate

From: Wholley, David (FNIH) [T] [b6]

Sent: Friday, February 5, 2021 9:39 AM

To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]

Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]

Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey

(FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T]

[b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

That seems fine to me.

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Friday, February 5, 2021 9:16 AM

To: Wholley, David (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];

Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6];

Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey

(FNIH) [T] [b6] Thompson, Katherine (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Hi David and Renate,

We've previously used the definitions below to distinguish ACTIV trials from ACTIV-associated trials – feel free to edit to your preference.

ACTIV trials = NIH, other federal agencies and ~20 industry and non-profit partners

ACTIV associated trials = NIH sponsored trials with one or more industry partners

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]

Sent: Thursday, February 4, 2021 8:39 PM

To: Myles, Renate (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]

Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Great. Happy to have my team review either or both.

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Thursday, February 4, 2021 8:37 PM

To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]

Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]

Subject: Re: Two Items for Your Input

Thanks, David. We can create the ACTIV table and can coordinate with our NIH colleagues on how best to describe ACTIV-like.

Thanks,
Renate

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health

[b6]

From: Wholley, David (FNIH) [T] [b6]

Sent: Thursday, February 4, 2021 8:22:15 PM

To: Myles, Renate (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6];
Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen
(NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T]
[b6]

Subject: RE: Two Items for Your Input

Renate: answers are as follows—

1. No, we have no current plans to turn the spreadsheets into a graphic table. You can do this, or we'd be happy to ask our Deloitte colleagues to do so. Please let me know. We will be happy to reach out to NIH colleagues as to how to describe the ACTIV-associated activities for the NIH ACTIV webpage, or better yet to point you to the right people at NIH to seek the information needed.
2. As for the AMP diagram, let me please circulate it to my team so we get you the exact timelines and funding numbers, at least as we see them. I see Ellens Wann and Gadbois are already copied on this note, so I will copy them on that reply so they can confirm the accuracy of our input.

Thanks, David

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Thursday, February 4, 2021 12:58 PM

To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];
Wojtowicz, Emma (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6];
Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen
(NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T]
[b6]

Subject: Two Items for Your Input

Hi David:

I hope this note finds you well. We need your input on two items, one ACTIV related and one AMP related.

1. Francis shared the excel sheet that lists the public ACTIV and ACTIV-like therapeutics in a simple table. Is FNIH developing a graphic table that we can post to the ACTIV page? We will need to also create an ACTIV-like item for the [ACTIV Therapeutics page](#), similar to the other ACTIV therapeutic projects. We would welcome your input on how best to describe ACTIV-like projects. As you may know, we have two national stories in the works on this, a 60 Minutes piece, which Francis will be filmed for next week, and a New Yorker piece, which has been in the works for several months and is expected to publish this month (FC will have his second interview the week of Feb. 15). We'd love to be able to point both outlets to the public graph ahead of the interviews. I'm sure you also saw the [Time profile on Francis](#), which includes a lot of information about ACTIV. We're hoping he makes the cover.
2. We are in the process of preparing the rollout for the AMP AD 2.0 announcement. We discussed the [current representation of the budget on the main AMP page](#) with Ellen Gadbois and Ellen Wann and thought that an updated version of the attached graph could replace the current budget table. We would only include current projects and AMP AD 2.0. I do think there are a few things that need to be fixed in the graph, such as showing when AD 1.0 ends, which I believe overlaps with when AD 2.0 begins. We would post the graph when we announce AD 2.0, currently scheduled for Feb. 18. Let us know if you are okay with this approach.

Thanks for your input.

Best,
Renate

Renate Myles, MBA

Security Directorate Affairs
of the Department of State has been
National Institute of Health
6 [b6]

From: George, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90BFFB4B3A2464382ADC29B127AED4E-GEORGEJIL]
Sent: 5/14/2020 12:07:09 PM
To: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Midnight? Oh my goodness...

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 12:06 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Francis,

This looked pretty clean! Each of us went over the JAMA proof independently and then compared notes. We have suggested a few minor fixes, as well as identified a couple of issues (mainly changes to the Figure by JAMA staff) that will need some input from you.

Attached is a PDF of the proof with our comments in sticky notes, and we've also listed our comments below for your convenience.

Rebecca & Ashley

Text

Page 1, Call-out Quote Placement. Perhaps would work better if it was placed one line higher or lower on the page. As is, it makes paragraph three rather difficult to read.

Page 1, Column 2, Paragraph 2, Final Sentence: Change agency name to: Department of Veterans Affairs (VA)

Note: It's no longer the Veterans Administration, <https://www.va.gov/>

Page 2, Column 1, Paragraph 2, Sentence 1. Add space between "The" and "Preclinical"

Page 2, Column 1, Paragraph 2, Sentence 3. It looks like a space may need to be added between "many" and "SARS"

Page 2, Column 1, Paragraph 3, Sentence 1. Change the name to: **The Therapeutics Clinical Working Group**

Page 2, Column 1&2, Final Sentence. **Note to FC:** Suggest cutting this sentence due to redundancy. It makes the same point as the preceding sentence, only in more general terms. Recommended cut is highlighted: "Of the 39 agents that underwent final prioritization review, the group identified 6 agents--including immunomodulators and supportive therapies--that it proposes to move forward into the master protocol clinical trial(s) expected to begin later in May. This working group has also developed a master protocol for clinical trials of prioritized therapeutic candidates."

Figure

Note: We are unaware of any follow-up communications between the authors and JAMA related to the Figure that was submitted. If there were such communications, some of our comments may not be relevant.

Top box(es). Submitted figure had the Partnership Leadership Group as a separate box to the left, connected by a dotted line to another box listing Executive Committee members. **Q for FC:** Does nesting the Executive Committee Box within the Partnership Leadership Group box work for you? Or should we ask JAMA to go back to the arrangement in your original figure?

Placement of "ACTIV database and inventory." Submitted figure had this text placed at the bottom in a banner with arrows indicating activities across working groups. This text now appears inside a static box in the middle, making it look (at least to our eyes) like it is a higher-level activity than those of the working groups. **Q to FC:** Does this change work for you? Or should we ask JAMA to go back to the arrangement in your original figure?

Working Group Names. Change "Therapeutics preclinical" to "Preclinical"

References

Qs to FC/Renate: Is the website that you want to cite in Reference 5 the ACTIV/RADx portal <<Scientists and Organizations can submit COVID-19 asset candidates to this portal>>? If so, we can add this URL. If not, cut "Portal" from Reference. If it is the new ACTIV webpage, do we have a placeholder URL, e.g., www.nih.gov/ACTIV, that we can provide to JAMA?

Additional Contributions

Change agency name from "the Veterans Administration" to "VA"

Note: It's now the Department of Veterans Affairs (VA), <https://www.va.gov/>

There are inconsistencies in what we spell out, Foundation for NIH, and what we abbreviate, e.g. NIAID, in this section. Not a big deal, but we may want to consider going with either all acronyms or all full names for the organizations listed.

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>

Sent: Wednesday, May 13, 2020 5:48 PM

To: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>; Kolberg, Rebecca (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>

Cc: Myles, Renate (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>; Burklow, John (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>; Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]>

Subject: FW: JAMA Viewpoint on ACTIV: please review

Hey Ashley and Rebecca,

Can you give these galley proofs a very close read, and let me know if you find anything amiss?

Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!

Francis

From: Stacy Christiansen <[REDACTED] b6 [REDACTED]>

Sent: Wednesday, May 13, 2020 5:22 PM

To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>

Cc: Howard Bauchner <[REDACTED] b6 [REDACTED]>; Karen Bucher <[REDACTED] b6 [REDACTED]>

Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,

Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

Thank you so much!

Best, Stacy

Stacy L. Christiansen, MA

Managing Editor, JAMA

Chair, AMA Manual of Style

Sent: 5/13/2020 8:20:44 PM
To: Rashid, Kamilah (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58ce52e57bb74034834aa8660b5c8677-rashidkl]
Subject: RE: COVID-19 Portal Roll-Out and All-Staff Blurb

I'm fine wioth

From: Rashid, Kamilah (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 4:19 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: COVID-19 Portal Roll-Out and All-Staff Blurb

I'm going to make some minor edits to the slide for consideration, sending shortly.

Kamilah

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Wednesday, May 13, 2020 at 4:12 PM
To: "Rashid, Kamilah (NIH/OD) [E]"; [b6]
Subject: RE: COVID-19 Portal Roll-Out and All-Staff Blurb

ICD meeting and he asked for a single slide.

From: Rashid, Kamilah (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 4:10 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: COVID-19 Portal Roll-Out and All-Staff Blurb

Ashley, quick question, where are these slides going to be posted?

Kamilah

From: "George, Jill (NIH/OD) [E]" [b6]
Date: Wednesday, May 13, 2020 at 4:05 PM
To: "Walsh, Elizabeth (NIH/OD) [E]" [b6]
Cc: "Rashid, Kamilah (NIH/OD) [E]" [b6], "Schwetz, Tara (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: RE: COVID-19 Portal Roll-Out and All-Staff Blurb

Is this better?

From: Walsh, Elizabeth (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 3:43 PM
To: Parker, Ashley (NIH/OD) [E] [b6], Schwetz, Tara (NIH/OD) [E] [b6], Rashid, Kamilah (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: Re: COVID-19 Portal Roll-Out and All-Staff Blurb

Perhaps it needs to be two slides. You can't see the part of the portal that asks for information about the candidates and technologies in this one.

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Wednesday, May 13, 2020 at 3:38 PM
To: "Schwetz, Tara (NIH/OD) [E]" [b6]; "Walsh, Elizabeth (NIH/OD) [E]" [b6]; "Rashid, Kamilah (NIH/OD) [E]" [b6]
Cc: "George, Jill (NIH/OD) [E]" [b6]
Subject: RE: COVID-19 Portal Roll-Out and All-Staff Blurb

Does the attached slide work?

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 3:30 PM
To: Schwetz, Tara (NIH/OD) [E] [b6]; Walsh, Elizabeth (NIH/OD) [E] [b6]; Rashid, Kamilah (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Portal Roll-Out and All-Staff Blurb

Hi Tara,

We are working on a slide and can share with the group for review. Does this sound ok?

Thanks,
Ashley

From: Schwetz, Tara (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 3:29 PM
To: Walsh, Elizabeth (NIH/OD) [E] [b6]; Rashid, Kamilah (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: COVID-19 Portal Roll-Out and All-Staff Blurb

Please draft up something simple describing the portal. Could be images describing the process.

Best,

Tara A. Schwetz, PhD
Acting Director, NINR
Associate Deputy Director, NIH
A: Building 1, Room 138
P: [b6] | M: [b6]

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Wednesday, May 13, 2020 at 2:06 PM
To: "Myles, Renate (NIH/OD) [E]" [b6]; "Parker, Ashley (NIH/OD) [E]" [b6]; Larry Tabak [b6]; "Wholley, David (FNIH) [T]" [b6]

Cc: "Burklow, John (NIH/OD) [E]" [b6], Tara Schwetz [b6]

Subject: RE: COVID-19 Portal Roll-Out and All-Staff Blurb

How about a slide on this for the presentation I am making to ICs tomorrow morning?

FC

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Wednesday, May 13, 2020 1:38 PM

To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6] Tabak,

Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: COVID-19 Portal Roll-Out and All-Staff Blurb

Hi Ashley:

Adding Tara. I know we want to alert our internal audiences first via leadership meetings this week and a mention in this week's all staff email, then socialize the portal with external groups.

Tara: thoughts on when it's okay to push to the information to ACTIV EC and working group members?

Thanks,

Renate

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Wednesday, May 13, 2020 12:20 PM

To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Wholley, David (FNIH) [T] [b6]

Cc: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]

Subject: Re: COVID-19 Portal Roll-Out and All-Staff Blurb

Hi Francis, Larry, and David,

I received notification that the portal [Scientists and Organizations can submit COVID-19 asset candidates to this portal](#) is now live and currently accessible on the NIH COVID-page. I am sure there is a communications plan to get the word out but should we move forward with sharing the link with the ACTIV EC, leadership team and working groups, ICDs, etc. and begin directing inquiries here?

Cc'ing Renate and John in case this is not recommended to share ahead of an official announcement. In the meantime, I am continuing to collect these from ES and FNIH.

Thank you and most excited to see this live!

Ashley

From: Walsh, Elizabeth (NIH/OD) [E] [b6]

Sent: Wednesday, May 13, 2020 11:54 AM

To: Parker, Ashley (NIH/OD) [E] [b6]

Cc: Rashid, Kamilah (NIH/OD) [E] [b6]

Subject: FW: COVID-19 Portal Roll-Out and All-Staff Blurb

FYI. The portal is living on this page:

<https://www.nih.gov/health-information/coronavirus>

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/12/2020 4:39:33 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Elsaid, Olivia [oelsaid@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]

Subject: Pre-call for ACTIV Executive Committee Call

Location: see webex below

Start: 5/18/2020 2:30:00 PM

End: 5/18/2020 3:00:00 PM

Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Elsaid, Olivia; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]

Optional Attendees: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]

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or go to [lync.com/joining](#)

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/12/2020 3:47:53 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]

Subject: Pre-call for ACTIV Leadership Call #4

Location: see webex below

Start: 6/1/2020 4:15:00 PM

End: 6/1/2020 5:15:00 PM

Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wholley, David; Menetski, Joseph; Adam, Stacey (FNIH) [T]; Santos, Michael (FNIH) [T]; Tountas, Karen (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Stratton, Ben, Tolman, Brett, Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

Join Webex meeting

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Dial **b6** @nih.webex.com

You can also dial [b6] and enter your meeting number.

Join by phone

Tap to call in from a mobile device (attendees only)

[b6] Call-in toll number (US/Canada)

Global call-in numbers

Join using Microsoft Lync or Microsoft Skype for Business

Dial [b6]@lync.webex.com

Get Lync or Skype

If you are a host, go here to view host information.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/12/2020 3:08:59 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [b6]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William [b6]; Stoffels, Paul [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b7f9577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Protasiewicz, Ann [b6]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Zanellato, Ann [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Sbbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
Subject: ACTIV Executive Committee Teleconference
Location: [https://fnih.zoom.us/j/\[b6\]](https://fnih.zoom.us/j/[b6])
Start: 5/20/2020 7:30:00 PM
End: 5/20/2020 9:00:00 PM
Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William, Stoffels, Paul, Woodcock, Janet (FDA/CDER); Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E], Wholley, David

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanelato, Ann; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/11/2020 2:41:22 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 5/12/2020 12:15:00 PM

End: 5/12/2020 12:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Tuesday from 8:30 AM to 9:00 AM

Required Attendees: Wholley, David (FNIH) [T], Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E];

Optional Attendees: Austin, Christopher (NIH/NCATS) [E]; Freire, Maria (FNIH) [T]; Parker, Ashley (NIH/OD) [E]

Attendees: Wood, Gretchen (NIH/OD) [E], McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]

Moving to 8:15 per Dr. Collins' request. -- Updated by Cheryl, May 11, 2020

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/11/2020 8:22:43 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Higgins, Joni C. [b6]; Danielle.Mauck@baycare.org
CC: Lewandowski, Amie [Amie.Lewandowski@baycare.org]

Subject: ACTIV and BayCare Health System (Florida)
Location: see webex below

Start: 5/15/2020 4:00:00 PM
End: 5/15/2020 4:30:00 PM
Show Time As: Tentative

Required Attendees: Wholley, David (FNIH) [T]; Tountas, Karen (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Higgins, Joni C.; [b6]
Optional Attendees: Lewandowski, Amie

United States, Eastern Standard Time

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[b6] Call-in toll number (US/Canada)

Global call-in numbers

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Dial [b6]@lync.webex.com

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/11/2020 8:22:42 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Higgins, Joni C.
CC: [b6] Danielle.Mauck@baycare.org
Lewandowski, Amie [Amie.Lewandowski@baycare.org]
Subject: ACTIV and BayCare Health System (Florida)
Location: see webex below
Start: 5/15/2020 4:00:00 PM
End: 5/15/2020 4:30:00 PM
Show Time As: Tentative

Required Attendees: Wholley, David (FNIH) [T]; Tountas, Karen (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Higgins, Joni C.; [b6]
Optional Attendees: Lewandowski, Amie

Join Webex meeting

Meeting number (access code) [b6] Meeting password: [b6]

Join from a video system or application

Dial [b6]@lync.webex.com

You can also dial [b6] and enter your meeting number.

Join by phone

Tap to call in from a mobile device (attendees only)

[b6] Call-in toll number (US/Canada)

Global call-in numbers

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Dial [b6]@lync.webex.com

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/6/2021 1:11:26 AM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmores]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Thomas Stock b6; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; David Douglas b6; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika b6; Lawlor, Ciarán [Lawlor.Ciaran@bcg.com]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris b6; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul b6; Kuethe, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Waring, Lorraine (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af91df8dec884f649cce10804470d1cb-Lorraine.Wa]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

b6

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US (San Jose)
US (Tacoma)
US (Houston)

Meeting ID: **b6**

Passcode: **b6**

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 2:27:39 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: FW: Biomarck -BIO-11006 ARDS compound for COVID 19
Attachments: Biomarck ARDS GOVERNMENT_April 2020 vF.PDF; Biomarck_Milken presentation_March 2020.pdf

FYI only.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 9:31 AM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Lane, Cliff (NIH/NIAID) [E] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: Biomarck -BIO-11006 ARDS compound for COVID 19

Hi, Stacey

I had a half-hour productive conversation with Esther Krofah and Brenda Honeycutt from Faster Cures yesterday to update them on ACTIV and hear what they are doing in the COVID field. She cited 1) their tracker for COVID therapeutics and vaccines (which I thanked her for making available, as we have been using it in our Tx prioritization efforts) 2) some policy work they are doing with NIH, primarily NCATS, and their business council around the COVID response, which she says will be posted later this week on their website 3) a post-COVID "early warning" surveillance system for future pandemics they are looking to develop 4) an analysis of promising compounds that could be used in platform trials. The Biomarck drug below has apparently risen to the top of the heap as she put it. They had a meeting with BARDA last week that Esther claimed showed good safety and efficacy data out of a Phase II. I am simply sending this to you and to Ashley so it gets on our respective "lists" of things to consider if it is not already on there.

Thanks, David

From: Esther Krofah [b6]
Sent: Monday, May 4, 2020 12:13 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: Biomarck -BIO-11006 ARDS compound for COVID 19

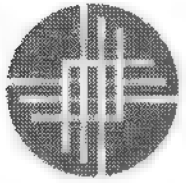
Hi David,

It was great speaking with you and thanks for all you're doing. As mentioned, Biomarck Pharmaceuticals based in Research Triangle Park, N.C. has an asset BIO-11006 that has the potential first to market treatment option in ARDS. They have received Orphan Drug designation from the FDA and expect to obtain priority review in ARDS. Their Phase 2 data demonstrated a mortality reduction of >40% in ARDS patients. Announcement of their results is [here](#): click here. The compound has a well-established clinical safety profile with over 200 patients exposed and there is strong interest in accelerating into clinical trial for COVID-19. Please see the attached documents. They had a meeting with BARDA last week that went well and have submitted their Phase 2 data to FDA. Application number: IND070296. This would be a worthwhile company to speak with and consider for acceleration in the ACTIV therapeutic accelerator. I am happy to make an introduction or see contact information below to the Chairman of the company.

Rajin Ahuja | Executive Chairman of the Board
Biomarck Pharmaceuticals - 2530 Meridian Parkway Suite 300, Durham, NC 27713
C: [b6] | biomarck.com

APAR0000017245

All the best,
Esther



MILKEN
INSTITUTE

Esther Krofah
Executive Director
FasterCures
+1 202-336-8906
(office)

b6



Sent: 5/6/2020 2:14:30 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]
Subject: RE: Draft JAMA article on ACTIV

b6

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Wednesday, May 6, 2020 9:53 AM
To: Lane, Cliff (NIH/NIAID) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Draft JAMA article on ACTIV

Additional suggestions.
Chris

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Wednesday, May 6, 2020 8:21 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Draft JAMA article on ACTIV

On the figure I would consider including master protocol under vaccines.

A few edits tracked.

Thanks for letting us take a look.

Cliff

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Tuesday, May 5, 2020 at 9:37 PM
To: "Freire, Maria (FNIH) [T]" [b6], "Wholley, David (FNIH) [T]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], Lawrence Tabak [b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: Draft JAMA article on ACTIV

In case you have time to look at it, here's the JAMA draft.

FC

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, May 5, 2020 9:16 PM
To: Stoffels, Paul [JJCUS] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]
Subject: Draft JAMA article on ACTIV

Hi Paul,

Attached, with much help from Ashley Parker and Rebecca Kolberg of my staff, is a draft of the proposed ACTIV article for JAMA. I also attach a Figure that will explain the structure of the effort. Please have a look and let me know what you think.

I'm looking forward to the Leadership Group meeting on ACTIV tomorrow at 3:30 PM EDT, and glad you are co-chairing with me!

Best, Francis

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/4/2020 8:11:23 PM
To: Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: ACTIV -- FNIH/NIH ICDs Follow-Up
Location: see webex below
Start: 5/6/2020 9:05:00 PM
End: 5/6/2020 9:30:00 PM
Show Time As: Tentative

Required Attendees: Wholley, David; Menetski, Joseph; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Santos, Michael (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Tumminia, Santa (NIH/NEI) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Glass, Roger (NIH/FIC) [E]; Tucci, Debara (NIH/NIDCD) [E]; Carter, Robert (NIH/NIAMS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Bianchi, Diana (NIH/NICHD) [E]; Anderson, James (NIH/OD) [E]; Norris, Andrea (NIH/CIT) [E]; Hodes, Richard (NIH/NIA) [E]; Volkow, Nora (NIH/NIDA) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Horsford, Jonathan (NIH/NIDCR) [E]; Schwetz, Tara (NIH/OD) [E]; Byrnes, Noni (NIH/CSR) [E]; Austin, Christopher (NIH/NCATS) [E]; Gregurick, Susan (NIH/OD) [E]; Wilder, Elizabeth (NIH/OD) [E]; Brennan, Patti (NIH/NLM) [E]; Sharpless, Norman (NIH/NCI) [E]; Freire, Maria (FNIH) [T]
Optional Attendees: Best, Cindy (NIH/NEI) [E]; Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Walker, Paula (NIH/NINDS) [E]; Stover, Kathleen (NIH/FIC) [E]; Hardesty, Rebecca (NIH/OD) [C]; Ott, Sandra (NIH/NICHD) [E]; Hughes, Karen (NIH/OD) [E]; Wade, Portia (NIH/CIT) [E]; Bronson, Charlette (NIH/NIA) [E]; Schulke, Hilda (NIH/NIDA) [E]; Shapiro-Loser, Beth (NIH/NIDDK) [E]; Mowery, Penny (NIH/NIDDK) [E]; Salley, Jasmine (NIH/NIDDK) [C]; New, Suzanne (NIH/NIDCR) [E]; Dzokoto-Pomenya, Caroline (NIH/OD) [C]; Hamid, Khawar (NIH/CSR) [E]; Lagos, Enrique (NIH/NCATS) [E]; Kellton, Karen (NIH/OD) [C]; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]

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Sent: 5/4/2020 5:12:21 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: FW: MEETING TODAY: NHLBI, NINDS -ACTIV Discussion

Will FNIH share any slides for the briefing with NHLBI and NINDS this afternoon at 4pm?

Thanks,
Ashley

From: McManus, Ayanna (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 12:39 PM
To: Simon, Dina (NIH/OD) [C] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Lagos, Enrique (NIH/NCATS) [E] [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Dimishkov, Roxanne (NIH/NHLBI) [C] [b6]
Subject: RE: MEETING TODAY: NHLBI, NINDS -ACTIV Discussion

Many thanks, all. We are confirmed for today at 4:45 PM. WeEx information has been sent to the calendars and can be found below:

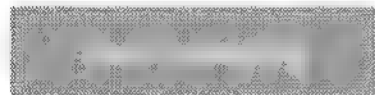
NHLBI, NINDS - ACTIV Discussion

Monday, May 4, 2020

4:45 pm | Eastern Daylight Time (New York, GMT-04:00) | 1 hr

Meeting number (access code) [b6]

Meeting password: [b6]



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[b6] (dina@nih.gov) [b6]
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From: McManus, Ayanna (NIH/OD) [E]

Sent: Monday, May 4, 2020 11:28 AM

To: Simon, Dina (NIH/OD) [C] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Lagos, Enrique (NIH/NCATS) [E] [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Dimishkov, Roxanne (NIH/NHLBI) [C] [b6]

Subject: RE: MEETING TODAY: NHLBI, NINDS -ACTIV Discussion

The meeting will not take place today at 11:45 AM. Aiming for 4:45 PM. Stay tuned.

From: McManus, Ayanna (NIH/OD) [E]

Sent: Monday, May 4, 2020 9:27 AM

To: Simon, Dina (NIH/OD) [C] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Lagos, Enrique (NIH/NCATS) [E] [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Dimishkov, Roxanne (NIH/NHLBI) [C] [b6]

Subject: MEETING TODAY: NHLBI, NINDS -ACTIV Discussion

Importance: High

Dear all,

I hope this email finds you well.

Dr. Collins is eager to convene a group to discuss NHLBI, NINDS -ACTIV. Please quickly provide availability [here](#). Drs. Gibbons and Koroshetz should feel free to include members of their leadership teams. If applicable, please let me know who the additional folks from NHLBI and NINDS will be.

All the best,

Ayanna

Ayanna L. McManus

Immediate Office of the Director

National Institutes of Health

Bethesda, MD 20892

Voice: [b6]

Fax: 301-402-2700

Email: [b6]

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Find your local number: <https://fnih.zoom.us> **b6**

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/4/2020 3:56:46 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]

Subject: Pre-call for ACTIV Leadership Call #4
Location: see webex below

Start: 5/18/2020 2:30:00 PM
End: 5/18/2020 3:00:00 PM
Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Elsaid, Olivia; Parker, Ashley (NIH/OD) [E]
Optional Attendees: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/4/2020 3:56:14 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]

Subject: Pre-call for ACTIV Leadership Call #3
Location: see webex below

Start: 5/4/2020 8:00:00 PM
End: 5/4/2020 8:30:00 PM
Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Parker, Ashley (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Elsaid, Olivia

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 3:38:22 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: FW: Control Arm for COVID-19 Trials
Attachments: Fact Sheet-Synthetic Control Database-_20191223.pdf; ASCO-Annual-Meeting_poster_20171020 (1).pdf

From: Freire, Maria (FNIH) [T] <[b6]>
Sent: Monday, May 4, 2020 11:28 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E]
Subject: FW: Control Arm for COVID-19 Trials

Ashley,

For your inclusion in your database.

WG – let me know if this is of any use for you. Otherwise I will reply that I have sent this to the NIH. M.

From: Donna Locke [b6]
Sent: Friday, May 1, 2020 10:22 AM
To: Freire, Maria (FNIH) [T] [b6]
Subject: Control Arm for COVID-19 Trials

Dear Dr. Freire,

I wanted to share with you how Medidata - Acorn AI can provide to the COVID-19 Industry trials a Control Arm for COVID-19.

50 percent of the clinical trials currently being run on COVID-19 utilize the Medidata-Acorn AI platform. With this data that is being collected, we can provide a Synthetic Control Arm to be utilized by the industry as a whole.

Many of your ACTIV participants are current customers of Medidata platform.

Rather than having each separate company try to create a Synthetic Control Arm themselves, we have the data. Would it make sense for Medidata-Acorn AI to provide this Control Arm for use industry-wide?

I understand in following COVID-19 news that the industry is struggling with having a Control Arm to compare trial data results to. We can provide this.

I have attached a Fact Sheet on our Synthetic Control along with our presentation at ASCO on the actual use of our solution.

We want to help, please tell us how we can.

Continued Health,
Donna Locke



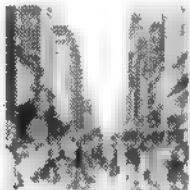
Donna Locke – Global Development Advisor – Enterprise

b6

| Cell:

b6

| Medidata Solutions



New York
NY USA

350 Hudson, New York City, New York

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From: Pollock, Rachel (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4887CB3513E242DFA7D2DF712DCC6D6A-POLLOCKRC]
Sent: 4/30/2020 3:00:22 PM
To: Whitfield, Michelle D. (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e428ea1fdc574614bcd5c42548b50c86-whitfieldmd]
CC: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: FW: Corvid-19 Vaccine Project Concept
Attachments: RE: Corvid-19 Vaccine Project Concept

For uploading in SAAVI.

Rachel Pollock

O: [b6]
C: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 10:57 AM
To: Pollock, Rachel (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: FW: Corvid-19 Vaccine Project Concept

FYI.

From: Meltzer, Abbey (FNIH) [T] [b6]
Sent: Thursday, April 30, 2020 10:18 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: Corvid-19 Vaccine Project Concept

Hi Ashley,

Here is another request that we received related to ACTIV.

Just out of curiosity, do you have an update as to when a link to a portal/database will be up and running to collect this information?

Best,
Abbey

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 4/30/2020 12:51:34 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Subject: RE: Corvid-19 Vaccine Project Concept

Abbey,

Isn't there an NIH mailbox set up for this type of thing? Do you have that?

Joe

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Thursday, April 30, 2020 8:49 AM
To: Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: Corvid-19 Vaccine Project Concept

Who should Dr. Bender send his concept to?

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Howard Jeffrey Bender [b6]
Sent: Wednesday, April 29, 2020 8:07 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: Corvid-19 Vaccine Project Concept

Hello, Cheryl -

I have a project concept for a Corvid-19 vaccine and would like to submit it to FNIH for consideration, but am not sure to whom it should go. Could you please send me the name and email address of the appropriate person?

Thanks very much! And stay healthy!

Cheers,

Howard

Howard Jeffrey Bender, Ph.D.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/4/2020 8:59:34 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Elsaid, Olivia [oelsaid@deloitte.com]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]

Subject: ACTIV Leadership Call Slide Review

Location: see webex below

Start: 5/4/2020 9:45:00 PM

End: 5/4/2020 10:15:00 PM

Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Elsaid, Olivia; Tabak, Lawrence (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]

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Sent: 5/4/2020 12:42:20 PM
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

NCATS and NIAID attend but include others (Gary—NHLBI, Ned—NCI, Walter—NINDS, Diana—NICHD, and Roger/Peter—FIC).

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Saturday, May 2, 2020 3:30 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

I think a combination of options 1 and 3 would be a good approach. David, do you see any problem with option 1?

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Saturday, May 2, 2020 1:59 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

A few suggestions to consider moving forward.

1. Invite the ICDs who asked to be participants of project #3 that came out of the 3/25 COVID science meeting to join the ACTIV leadership meetings happening twice per month. NCATS and NIAID attend but include others (Gary—NHLBI, Ned—NCI, Walter—NINDS, Diana—NICHD, and Roger/Peter—FIC).
2. Option 2 would be to meet with them regularly (twice per month?) to provide updates — may not be preferred given the limited bandwidth with your/LATs schedule.
3. Option 3 provide “brief” updates to the larger ICD group regularly (twice per month?) — this would not substitute for option 1 but be in addition to.

Thanks,
Ashley

On May 2, 2020, at 9:13 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Sorry that wasn't clear. Need to start with NHLBI. Gary agreed to that.

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Saturday, May 2, 2020 9:03 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E]

b6

Subject: Re: COVID19-ROA-OTA-FINAL.pdf

To be clear, do you want a special ICDs meeting to review ACTIV with all of them, or a meeting with senior NHLBI staff?

Thanks

Larry

From: Francis Collins <b6>

Date: Saturday, May 2, 2020 at 8:27 AM

To: "Tabak, Lawrence (NIH/OD) [E]" <b6>, "Parker, Ashley (NIH/OD) [E]" <b6>, "Wholley, David (FNIH) [T]" <b6>, "Adam, Stacey (FNIH) [T]" <b6>, "Tountas, Karen (FNIH) [T]" <b6>, "Austin, Christopher (NIH/NCATS) [E]" <b6>

Subject: RE: COVID19-ROA-OTA-FINAL.pdf

Hi all, (somehow this was stuck in my outbox from yesterday afternoon)

I spoke with Gary Gibbons just now. I'm glad we connected because there is a fairly serious issue here. The NHLBI ROA on host-targeted therapies for COVID-19 was planned before ACTIV came into being. Gary and colleagues thought it was their responsibility to act quickly to harness the clinical trial capacity of PETAL and other networks that they support. That was of course a highly appropriate response to the crisis, and that's how they got their HCQ trial started.

It's clear, however, that Gary is not very well informed about ACTIV. He says David Goff has been giving him occasional updates, but David is very stretched by other duties. I told Gary he is welcome to add another representative so that could be better informed about the Clinical Therapeutics and Clinical Trials Capacity Working Groups.

He says the ROA has created a buzz in his clinical community, who are largely unaware of ACTIV. I tried to fill him in on where we are with the candidate therapeutic prioritization, the master protocol, and the capacity survey. He said that the PIs of NHLBI's networks might not take kindly to a master protocol that they hadn't had input to. I pushed back that this is not the time for academic squabbles that consume months, but a bit of command and control will be needed. He acknowledged that and said he had been preparing the ground for that to happen.

He was clearly suggesting that IC Directors should be better informed about ACTIV. In his case, that's definitely true.

I suggested there should be a meeting early next week where he and his senior staff involved in clinical trials could go over all of these issues and get fully briefed by relevant ACTIV co-chairs about the status of these efforts and the timetables involved.

Can we work on setting that up?

Francis

APAR0000017300

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 11:44 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E]
[b6]; Wholley, David (FNIH) [T] [b6]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

On it

From: Francis Collins [b6]
Date: Thursday, April 30, 2020 at 11:43 AM
To: "Parker, Ashley (NIH/OD) [E]" [b6] "Tabak, Lawrence (NIH/OD) [E]"
[b6], "Wholley, David (FNIH) [T]" [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

So this is puzzling. Yes, Larry, please reach out to Gary.

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 11:16 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
[b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

Yes, we have him listed on the clinical capacity WG.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 11:11 AM
To: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
[b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

First I am seeing also. Isn't David Goff of NHLBI on ACTIV?

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 10:46 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

First I am seeing this. Francis, do you want me to reach out to Gary?

From: "Wholley, David (FNIH) [T]" [b6]
Date: Thursday, April 30, 2020 at 10:34 AM
To: Francis Collins [b6]; "Tabak, Lawrence (NIH/OD) [E]"
[b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

Francis and Larry:

Perhaps I am misunderstanding the intent of this announcement but it seems more than a little duplicative of what we are trying to do in ACTIV. My co-chairs certainly seem to think so. Can someone offer a perspective we can communicate on this please? Thanks, David

From: "Read, Sarah (NIH/NIAID) [E]" [b6]
Date: April 29, 2020 at 10:45:05 PM EDT
To: "Adam, Stacey (FNIH) [T]" [b6], Eric Hughes
[b6]
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

This is interesting. I can't figure out the date of when this was published but it reads like a funding announcement for ACTIV...minus antivirals.

<https://www.nhlbi.nih.gov/sites/default/files/media/docs/COVID19-ROA-OTA-FINAL.pdf>

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/1/2020 1:33:23 PM
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]
Subject: ACTIV Response Partnership Leadership Team Meeting #4
Location: <https://fnih.zoom.us/j/912138fd-gladmanjt> b6
Start: 5/20/2020 7:30:00 PM
End: 5/20/2020 9:00:00 PM
Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Doisten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramon; Plenge, Robert; Talley, Michael
Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose; Zottoli, Jessica; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]

Join Zoom Meeting
<https://fnih.zoom.us/j/912138fd-gladmanjt> b6

Meeting ID: b6

Password: b6

One tap mobile

b6 US (Chicago)
US (New York)

Dial by your location

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US (Chicago)
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US (Tacoma)
US (Houston)
US (San Jose)
US (San Jose)

Meeting ID: b6

Password: b6

Find your local number: <https://fnih.zoom.us/j/912138fd-gladmanjt> b6

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 4/26/2020 4:54:15 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Fwd: repurposed oncology drug shows in-vitro activity with COVID-19
Attachments: image001.png; ATT00001.htm; image002.png; ATT00002.htm; image003.png; ATT00003.htm; image004.png; ATT00004.htm; image005.png; ATT00005.htm; image006.png; ATT00006.htm; image007.png; ATT00007.htm; Quad chart.pdf; ATT00008.htm; CONCEPT PAPER - Reducing ARDS and Pneumonia of Acute Viremia with ST-001 (nanoFENRETINIDE IV).pdf; ATT00009.htm

Ashley,

I will start sending you these. Best, Maria

Begin forwarded message:

From: "Earle T. Holsapple" [b6]
Date: April 26, 2020 at 11:06:38 AM GMT-5
To: "Freire, Maria (FNIH) [T]" [b6]
Cc: Brian Leyland-Jones [b6]
Subject: repurposed oncology drug shows in-vitro activity with COVID-19

Dear Dr. Freire:

We are writing you to seek advice in determining how our clinic-ready, repurposed oncology drug, for use in treating COVID-19, can receive a quick evaluation and, hopefully, be added to the list of therapeutic candidates that meet ACTIV's requisites for consideration.

SciTech Development, LLC (SciTech) is a clinical stage, biopharmaceutical company that has reformulated a well-known and highly-studied, safe retinoid, fenretinide, by overcoming its bioavailability shortcoming. SciTech's lead product, ST-001 nanoFenretinide, is clinic ready (IND in hand for a non-Hodgkin's lymphoma trial).

Published data makes the case for fenretinide and, by inference, ST-001's use in treating COVID-19. Fenretinide and/or ST-001 have recently demonstrated antiviral activity against SARS-CoV-2 and MERS-CoV-2 and also previously against Dengue, Zika, West Nile, and HIV, viruses. This recorded antiviral activity and its likely immune effects, taken in conjunction with the API's known safety and tolerability profile, makes it an ideal candidate to repurpose for

use with COVID-19. We are attaching two one-page documents that quickly summarize the opportunity and MoAs (We suggest these are read before proceeding).

SciTech filed a white paper with both BARDA and NIAID several weeks ago and have heard nothing since. We believe this therapeutic opportunity is too important and timely to be lost in a long review process and warrants immediate consideration.

The development of ST-001 as a drug to treat COVID-19 finds alignment with the medical countermeasure goals of BARDA and the strategic goals of PHEMCE through four key features of our proposition:

1. Early availability to the US healthcare system,
2. Fenretinide and/or ST-001's demonstrated efficacy profile versus Coronaviruses,
3. Readiness of large-scale production upon positive clinical evaluation of ST-001, and
4. Broad impact of proposed clinical investigations beyond COVID-19.

SciTech is presently in negotiations with two large, Midwest healthcare systems to conduct the clinical trial. Last Friday, the company filed a pre-IND application, that cross files with our active IND, for the use of ST-001 in treating COVID-19 patients. We are poised to act quickly and would greatly benefit from government support and/or corporate collaboration.

The rapidly expanding insights into clinical (in particular ICU) care for COVID-19 patients, their pathologic processes and parameters, and SARS-CoV-2 processes unveiled three key drivers of the disease that are direct targets of fenretinide. First, direct inhibition of viral replication would decrease viremia. Second, COVID-19 is strongly associated with increases of both IL-6 and IL-22 immune pathways, reportedly with detrimental implications in some patients (i.e. cytokine storm). SciTech hypothesizes that IL-6 and IL-22 can be controlled by Fenretinide directly inhibiting inflammation and resulting cytokine storm damage. Third, direct communications with critical care physicians and recent research indicate that free radicals might cause organ damage due to an inability to neutralize these. Fenretinide acts as an antioxidant.

Based on the above, we would appreciate guidance on the best approach for receiving serious consideration of our promising COVID-19 therapeutic.

Respectfully seeking your guidance,

Brian Leyland-Jones, MD, PhD
Chief Medical Officer

b6

Earle T. Holsapple

President

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/28/2020 10:59:32 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Message Recall Success: Update ACTIV Partner Slide

Your message

To: Wholley, David (FNIH) [T]
CC: Collins, Francis (NIH/OD) [E]; George, Jill (NIH/OD) [E]
Subject: Update ACTIV Partner Slide
Sent: 4/28/2020 10:59:20 PM

was successfully recalled on 4/28/2020 10:59:31 PM

Sent: 4/28/2020 2:42:07 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: WH_ACTIV_042920 Updated.pptx

There's a lot happening this morning – Speeches will be moved to a different time BTW.

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 10:41 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: WH_ACTIV_042920 Updated.pptx

This will take time. I won't have it done before our 11am meeting.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 10:40 AM
To: George, Jill (NIH/OD) [E] [b6]
Subject: RE: WH_ACTIV_042920 Updated.pptx

Comparing them to the BARDA logo/text – they do not look as visually clear. It's likely the application tool used to pull the logo.

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 10:37 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: WH_ACTIV_042920 Updated.pptx

What is wrong with them?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 10:34 AM
To: George, Jill (NIH/OD) [E] [b6]
Subject: RE: WH_ACTIV_042920 Updated.pptx

OK.

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 10:33 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: WH_ACTIV_042920 Updated.pptx

After I get this meeting packet out

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 10:21 AM
To: George, Jill (NIH/OD) [E] [b6]
Subject: RE: WH_ACTIV_042920 Updated.pptx

When will you have more time? – the NIH logos need better images as well.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 10:16 AM
To: George, Jill (NIH/OD) [E] [b6]
Subject: RE: WH_ACTIV_042920 Updated.pptx

Totally understood – thanks!

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 10:14 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: WH_ACTIV_042920 Updated.pptx

Hope this helps!
Sorry I couldn't chat. Trying to get materials out the door for our 11:00.
Thanks,
Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 10:00 AM
To: George, Jill (NIH/OD) [E] [b6]
Subject: Re: WH_ACTIV_042920 Updated.pptx

Hi Jill,

Unfortunately, Francis will only be able to use 2 slides for the WH briefing tomorrow. Can you please help with formatting slide 1 by providing better/crisp visuals of the agencies where needed? Also, Gary Disbrow and Robert Johnson work for BARDA – I think it's better to use the BARDA logo versus the HHS logo.

Anything else you notice.

Thank you,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, April 28, 2020 9:47 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: WH_ACTIV_042920 Updated.pptx

Here you go, this is updated.

Sent: 4/28/2020 9:11:29 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd], Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: DoD Representatives
Attachments: WH_ACTIV_042920 Updated 509pm.pptx

Please attached.

-----Original Message-----

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, April 28, 2020 5:10 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E]
Subject: RE: DoD Representatives

Given Ashley has answered you on this I assume she is working it. Let me know if I am mistaken.

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 5:05 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: DoD Representatives

Can I get this ASAP? Otherwise I'm going to miss the window for the WH slides....

-----Original Message-----

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, April 28, 2020 4:31 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: FW: DoD Representatives

Can we quickly add Brigadier General Talley and DoD to the ACTIV roster slide? I'd like to be able to show we're connected -- BG Talley will be in the room tomorrow at the WH.

FC

-----Original Message-----

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Tuesday, April 28, 2020 4:26 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
[b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T]
Subject: DoD Representatives

BG Talley concurs with the following nominees to support the ACTIV initiative:

Executive Group: BG Talley (Dr. Dertzbaugh backup),

[b6]
Preclinical: [b6] USAMRIID, [b6]

Clinical: CAPT Tim Burgess, USUHS, [b6]

Vaccines: [b6] WRAIR, [b6]

Sent: 4/28/2020 9:10:45 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd], Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: DoD Representatives
Attachments: WH_ACTIV_042920 Updated 506PM.pptx

Jill was working on reformatting you can use this version

-----Original Message-----

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, April 28, 2020 5:10 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E]
Subject: RE: DoD Representatives

Given Ashley has answered you on this I assume she is working it. Let me know if I am mistaken.

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 5:05 PM
To: Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Wholley, David (FNIH) [T] [b6]
Subject: RE: DoD Representatives

Can I get this ASAP? Otherwise I'm going to miss the window for the WH slides....

-----Original Message-----

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, April 28, 2020 4:31 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: FW: DoD Representatives

Can we quickly add Brigadier General Talley and DoD to the ACTIV roster slide? I'd like to be able to show we're connected -- BG Talley will be in the room tomorrow at the WH.

FC

-----Original Message-----

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Tuesday, April 28, 2020 4:26 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
[b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T]
Subject: DoD Representatives

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[b6]

Preclinical: [b6] USAMRIID, [b6]

Clinical: CAPT Tim Burgess, USUHS, [b6]

Vaccines: [b6] WRAIR, [b6]

Sent: 4/27/2020 9:37:30 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf], Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: RE: PLEASE READ: Call to action for NIH initiative ACTIV – seeking clinical trial Network and Site information

That's correct. I think David was cross checking with Karen to ensure she didn't

Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 5:32 PM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tountas, Karen (FNIH) [T] [b6]
Subject: RE: PLEASE READ: Call to action for NIH initiative ACTIV – seeking clinical trial Network and Site information

OK, maybe I was confused, but I thought this was sent to me for me to send. So I did.

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, April 27, 2020 3:52 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Tountas, Karen (FNIH) [T] [b6]
Subject: RE: PLEASE READ: Call to action for NIH initiative ACTIV – seeking clinical trial Network and Site information

Hi Ashley--It looks fine to me. Karen, any issues? (If you don't hear from Karen in the next 30 minutes, please just press send.) Thanks

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 3:32 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: PLEASE READ: Call to action for NIH initiative ACTIV – seeking clinical trial Network and Site information

Assisting with getting this into a format that is easier to send. Please see note and attachments to forward to the survey recipients on behalf of the clinical capacity WG – I've deleted the email trail below for ease of sending.

To:

Bcc: [b6]

b6

b6

b6

Cc: Wholley, David (FNIH) [T] b6 Tountas, Karen (FNIH) [T] b6

Subject line: Call to action for NIH initiative ACTIV – seeking clinical trial Network and Site information

Dear Colleague,

The National Institutes of Health (NIH) announced on April 17 the formation of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, a collaboration among HHS agencies, biopharmaceutical companies, and other partners to develop a coordinated international research strategy to respond to the COVID-19 crisis. **ACTIV needs your help to identify clinical trial sites that might be able to participate in urgent COVID-19 research.**

I am specifically asking that you take a few moments to respond to **two important requests**. The first is a Network-level Survey (see link below) that aims to capture the capacity and capabilities of your clinical trial network overall (**please reply by Thursday, April 30, 2020**)

(<https://forms.office.com/Pages/ResponsePage.aspx?id=eHW3FHOX1UKFByUcotwrBryIKqh49V5CqfAO1I8UUONUN0FU-MzdEMVIPSU5QQVpHVzJLRFQ5OVc1Ry4u>).

In addition, I ask that you send the more detailed Site-level Survey in the (second) link below to the appropriate contact at your sites to provide more detailed information on the capacity and capabilities of individual network sites (**reply due by Monday, May 4, 2020**)

(<https://forms.office.com/Pages/ResponsePage.aspx?id=eHW3FHOX1UKFByUcotwrBryIKqh49V5CqfAO1I8UUONUOUw3RzdEUlFBN08zN0tQMzZENIUwNUQxRy4u>). A PDF version of each survey is attached to facilitate information gathering prior to entering the online survey.

These surveys will be used by our ACTIVE Clinical Trial Capacity Working Group (a group of ~15 scientific experts drawn from NIH, FDA, industry, and academic institutions) to develop an inventory of key networks and sites that can be used to expedite clinical trials for COVID-19.

I want to thank you and your colleagues in advance for submitting these surveys so quickly. If you have any questions about the surveys or their use in ACTIV, please contact Dr. Karen Tountas at the FNIH (ktountas@fnih.org) directly.

Best regards,

Francis S. Collins, M.D., Ph.D.
Director, NIH

Sent: 4/27/2020 9:33:32 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd], Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: clinical therapeutics and vaccine candidate agent information received in emails by NIH

Hi David,

I shared the updated spreadsheet as of Friday with OD leadership for review. I think we can develop a schedule to get these to you or the working group co-chairs on Fridays after Francis and Larry has had the opportunity to review.

I've added several today that Maria and others have shared and I would prefer to provide this version. Let me check-in with Francis on this and I will send you the updated spreadsheet.

Thank you,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, April 27, 2020 4:58 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: clinical therapeutics and vaccine candidate agent information received in emails by NIH

Hi Ashley and Larry:

I recall from our war room call last Wednesday or Thursday morning that we agreed (in response to your question, Larry) that the Tx-Clinical Agent Prioritization SubGroup would regularly receive information you have collected from emails and other sources who have approached NIH regarding agents or vaccine candidates that might be of interest to ACTIV. We requested that the initial list of things you have and any relevant associated info be batched up and sent to FNIH every Friday—beginning this past Friday the 24th. My team just reminded me we have not seen anything yet. There is interest in seeing this also from the Tx-Preclinical WG by the way. Can you please let me know what the plan would be to start getting this to us?

Thanks,
David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

Subject: FW: clinical therapeutics and vaccine candidate agent information received in emails by NIH

Hi Francis,

Before we respond to David, I want to ensure we have a plan for sharing the email inquiries with the working groups.

Are you ready to start sharing these spreadsheets with the ACTIV working groups? If so, I can start sending the updated spreadsheets to David and the co-chairs on Friday's after you've had a chance to review.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]

Sent: Monday, April 27, 2020 4:58 PM

To: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Subject: clinical therapeutics and vaccine candidate agent information received in emails by NIH

Hi Ashley and Larry:

I recall from our war room call last Wednesday or Thursday morning that we agreed (in response to your question, Larry) that the Tx-Clinical Agent Prioritization SubGroup would regularly receive information you have collected from emails and other sources who have approached NIH regarding agents or vaccine candidates that might be of interest to ACTIV. We requested that the initial list of things you have and any relevant associated info be batched up and sent to FNIH every Friday—beginning this past Friday the 24th. My team just reminded me we have not seen anything yet. There is interest in seeing this also from the Tx-Preclinical WG by the way. Can you please let me know what the plan would be to start getting this to us?

Thanks,
David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

[b6]

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/3/2021 6:21:54 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [erica@lji.org]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Treia (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [cjreich@health.ucsd.edu]; Lisbeth Jørgensen [lisbeth.joergensen.04@regionh.dk]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [dana.carluccio@roseliassociates.com]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina

[b6] Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: ACTIV-2/3 Trial Oversight Committee Meeting

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210203.pdf

Location: https://fnih.zoom.us/[b6]

Start: 2/3/2021 8:00:00 PM

End: 2/3/2021 9:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Neaton, Jim; Lundgren, Jens; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Sorosa, Alex; Chen, Helen; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Dear All,

Please find attached the slides for today's meeting.

Thanks,
Stacey

Join Zoom Meeting
https://fnih.zoom.us/[b6]

Meeting ID: [b6]
Passcode: [b6]
One tap mobile

[b6] US (Chicago)
US (New York)

Dial by your location
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US (New York)
US (Washington D.C.)
US (Tacoma)
US (Houston)
US (San Jose)
US (San Jose)

Meeting ID: [b6]
Passcode: [b6]
Find your local number: https://fnih.zoom.us/[b6]

Sent: 4/24/2020 8:59:12 PM
To: Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: ACTIV Proposal for COVID lung injury

Hi Rachel,

Can you please upload the email below?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, April 24, 2020 4:56 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]
Subject: FW: ACTIV Proposal for COVID lung injury

From: Gabor Illei [b6]
Sent: Friday, April 24, 2020 4:30 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: ACTIV Proposal for COVID lung injury

Dear David,

Kristina Lu from NIAID suggested I contact you. I am VP of clinical development at Viela Bio, a biotechnology company in Gaithersburg with a focus on autoimmune diseases. We believe that there is a strong rationale supporting the potential of one of our clinical stage assets to prevent or treat the hyperinflammatory syndrome leading to acute lung injury in COVID patients. I read with great interest about the ACTIV initiative and would like to find out more about how proposals can be submitted for consideration for ACTIV. Can you provide me some information or direct me to where I can get this information?

Thank you very much.
Best regards,
Gabor

Gábor Illei, MD, PhD, MHS
Vice President
Clinical Development Lead



[b6]

From: Lu, Kristina (NIH/NIAID) [E] [b6]
Sent: Wednesday, April 22, 2020 6:35 PM
To: Gabor Illei [b6]
Cc: Bill Rees [b6]; Michael Smith [b6]; Ilias Alevizos [b6];
Sandra Gallagher [b6]
Subject: Re: Proposal for VIB7734 for COVID lung injury

EXTERNAL. Do not open attachment(s) unless you know the content is safe.

Hello Gabor,

There was a recent NIH news release regarding the ACTIV partnership. For additional information, please contact David Wholley [b6], who is the FNIH Contact for ACTIV (Public-Private Partnership Initiative).

--Kristina

From: Gabor Illei [b6]
Date: Wednesday, April 22, 2020 at 11:48 AM
To: "Lu, Kristina (NIH/NIAID) [E]" [b6]
Cc: Bill Rees [b6], Michael Smith [b6], Ilias Alevizos [b6], Sandra Gallagher [b6]
Subject: RE: Proposal for VIB7734 for COVID lung injury

Dear Kristina,

I would like to follow up to see if the NIAID's SARS-CoV-2/COVID-19 research team had a chance to review our proposal for the prevention and treatment of COVID-19 associated acute lung injury. We are not primarily looking funding but for an effective mechanism where we could test our asset in an expeditious an effective way. We read with great interest about the ACTIV initiative organized by the NIH but were unable to find any specifics about how one could submit a proposal or an asset to this program. Can you give us some advice on how to apply or who to contact to find out more details?

Any advice is greatly appreciated.

Thank you and best regards,

Gabor

Gábor Illei, MD, PhD, MHS
Vice President
Clinical Development Lead



[b6]

From: Gabor Illei
Sent: Monday, April 13, 2020 5:45 PM

APAR0000017401

To: Lu, Kristina (NIH/NIAID) [E] [b6]
Cc: Bill Rees [b6]; Michael Smith [b6]; Ilias Alevizos [b6]
Sandra Gallagher [b6]
Subject: RE: Proposal for VIB7734 for COVID lung injury

Dear Kristina,

Thank you for the prompt response. We are looking forward to hearing some feedback NIAID's SARS-CoV-2/COVID-19 research team. We will also look at the IDCRC website.

Best regards,
Gabor

From: Lu, Kristina (NIH/NIAID) [E] [b6]
Sent: Monday, April 13, 2020 5:06 PM
To: Gabor Illei [b6]
Cc: Bill Rees [b6]; Michael Smith [b6]; Ilias Alevizos [b6]
Sandra Gallagher [b6]
Subject: Re: Proposal for VIB7734 for COVID lung injury

EXTERNAL. Do not open attachment(s) unless you know the content is safe.

Hello Dr. Illei,

Thank you for your message regarding a clinical trial with VIB7734 for the prevention and treatment of COVID-19 associated lung injury and sharing your slide decks. Your email will be shared with NIAID's SARS-CoV-2/COVID-19 research team.

NIAID supports clinical trials through our Infectious Diseases Clinical Research Consortium (IDCRC) and our investigator-initiated clinical trial grant programs. The IDCRC recently launched a website for investigators interested in submitting concepts for consideration. This website is <https://med.emory.edu/departments/medicine/divisions/infectious-diseases/idcrc/concept.html>

For investigator-initiated grants, we are directing PIs to the parent mechanisms listed below:

- NIAID Clinical Trial Implementation Cooperative Agreement (U01, Clinical Trial Required)
- Parent R01 announcement:
 - NIH Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)
 - Research Project Grant (Parent R01 Clinical Trial Required)
- Parent R21 announcement:
 - NIH Exploratory/Developmental Research Grant Program (Parent R21 Basic Experimental Studies with Humans Required)
 - NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)

Funding opportunities are also available from other NIH Institutes and Centers. Please see the table on this website https://grants.nih.gov/grants/natural_disasters/corona-virus.htm.

Kind regards,
Kristina

--

Kristina T. Lu, PhD

APAR0000017401

Program Officer
Respiratory Diseases Branch
Division of Microbiology & Infectious Diseases
NIAID | NIH | DHHS

b6

Disclaimer: The information in this email and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the originally intended recipient. If you have received this email in error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of NIAID by one of its representatives.

From: Gabor Illei [b6]
Date: Monday, April 13, 2020 at 12:32 PM
To: "Lu, Kristina (NIH/NIAID) [E]" <[b6]>, "Bozick, Brooke (NIH/OD) [E]"
[b6]
Cc: Bill Rees [b6], Michael Smith [b6], Ilias Alevizos
[b6], Sandra Gallagher [b6]
Subject: FW: Proposal for VIB7734 for COVID lung injury

Dear Drs. Lu and Bozick,

I am the VP for clinical development of VielaBio, a biotechnology company in Gaithersburg with a focus on autoimmune diseases. We believe that there is a strong rationale supporting the potential of one of our clinical stage assets (a plasmacytoid depleting cell antibody) to prevent or treat the hyperinflammatory syndrome leading to acute lung injury in COVID patients.

We would like to test our asset in clinical trials as soon as possible and wanted to ask if NIAID had any mechanisms to facilitate a clinical trial. Could this molecule be considered for a platform study? Are there any other options for early stage molecules? (We are currently completing dosing in the last cohort of cutaneous lupus patients in a multiple ascending dose Phase 1b study).

I attached a brief high level description of our plans and a slide deck with more details on the rationale and plans. These slides were also submitted to BARDA and we submitted an application to the FDA CTAP program. Please note that the attached slides contain Viela's confidential information. As is usually expected, please protect the confidentiality of these slides just as you do for your institution's confidential information and please do not share the slides without asking Viela first.

We are not currently and have not in the past received any NIH funding.

Please let me know if you have any questions. I am looking forward to your response, we would greatly appreciate any information.

Thank you and best regards,
Gabor

Gábor Illei, MD, PhD, MHS
Vice President
Clinical Development Lead



b6

APAR0000017401

From: Read, Sarah (NIH/NIAID) [E] [b6]
Sent: Thursday, April 9, 2020 11:14 AM
To: Gabor Illei [b6]; Michael Smith [b6]
Cc: Bill Rees [b6]
Subject: RE: Proposal for VIB7734 for COVID lung injury

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Hi again Gabor and Mike,
I apologize for the delay getting back to you. Please contact Kristina Lu ([b6]) and Brooke Bozick [b6] at the Division of Microbiology and Infectious Diseases to make this inquiry.

Best wishes,
Sarah

From: Read, Sarah (NIH/NIAID) [E]
Sent: Monday, April 6, 2020 7:58 AM
To: Gabor Illei [b6]; Michael Smith [b6]
Cc: Bill Rees [b6]
Subject: RE: Proposal for VIB7734 for COVID lung injury

Hi Gabor and Mike, I'm just waiting on a contact from Division of Microbiology and Infectious Diseases. They are reorganizing a bit given how many inquiries they are receiving and are identifying a new contact for immunotherapies. Will send you contact information later today.

Best,
Sarah

From: Gabor Illei [b6]
Sent: Sunday, April 5, 2020 11:28 AM
To: Read, Sarah (NIH/NIAID) [E] [b6]; Michael Smith [b6]
Cc: Bill Rees [b6]
Subject: RE: Proposal for VIB7734 for COVID lung injury

Dear Sarah,

Thank you for your prompt response. Mike, thank you for making the connection.
To answer your question, we are not currently and have not in the past received any NIH funding. We have submitted a BARDA TechWatch meeting request and will apply to the FDA CTAP program. We are also trying to explore any other possibilities which may facilitate starting a clinical study.
Any suggestion would be greatly appreciated.
Thank you,
Gabor

Gábor Illei, MD, PhD, MHS
Vice President
Clinical Development Lead

b6

From: Read, Sarah (NIH/NIAID) [E] b6
Sent: Sunday, April 5, 2020 10:58 AM
To: Michael Smith b6
Cc: Bill Rees b6; Gabor Illei b6
Subject: Re: Proposal for VIB7734 for COVID lung injury

EXTERNAL. Do not open attachment(s) unless you know the content is safe.

Hi Mike.

Thank you for your email. All is well with us, relatively speaking. We're adjusting to a new normal and hoping/waiting for things to improve.

This is not exactly my purview. As you know my division's primary focus is HIV but like many research organizations we've pivoted to SARS-COV2 research but mainly evaluation of interventions approved for other indications (eg hydroxychloroquine, remdesivir, etc). However I can find the appropriate NIAID contact for you. Will you tell me first do you have any current NIH funding of any kind (not specifically for SARS-COV2) or have you previously?

Thank you for your interest in helping with the SARS-COV2 response.

Best,
Sarah

From: "Michael Smith" b6
Date: Saturday, April 4, 2020 at 10:19:11 PM
To: "Read, Sarah (NIH/NIAID) [E]" b6
Cc: "Bill Rees" b6; "Gabor Illei" b6
Subject: Proposal for VIB7734 for COVID lung injury

Hi Sarah!

This is Mike Smith, Charlotte's neighbor from Golf Course Square. I hope you and your family are doing well. We are doing pretty good over here, although Rachel is starting to see some patients infected with SARS-CoV-2 at her ER in Korea right now. I'm a little worried about her. I'm glad you all have Charlotte pretty well taken care of.

I am sorry to bother you during what has to be an extremely busy time, but we would like to ask for your advice on how to advance one of our clinical stage assets (a plasmacytoid depleting cell antibody) to clinical trial to prevent or treat COVID associated lung injury. I attached both a brief summary of the proposal and an expanded powerpoint deck with more details. I've also cc'd Gabor Illei, our Vice President of Clinical Development, and Bill Rees, head of Translational Sciences here at Viela Bio.

If this is outside your purview could you advise who best to contact or feel free to forward this message or deck.

My apologies again for bothering you. We are eager to find out if we can help somehow in the fight against COVID.
Thank you!
Mike Smith
.

Please note that the attached slides contain Viela's confidential information. As is usually expected, please protect the confidentiality of these slides just as you do for your institution's confidential information and please do not share the slides without asking Viela first.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 4/23/2020 8:51:51 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 4/30/2020 9:00:00 PM

End: 4/30/2020 9:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Thursday from 2:30 PM to 3:00 PM

Required Attendees: Wholley, David (FNIH) [T], Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E];

Optional Attendees: Austin, Christopher (NIH/NCATS) [E]; Freire, Maria (FNIH) [T]; Parker, Ashley (NIH/OD) [E]

Attendees: Wood, Gretchen (NIH/OD) [E], McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

Sent: 4/22/2020 5:42:59 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd], Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: Preparation for HEVER COVID-19 call

Yes, we are handling moving these into Francis' slide template and will trim as needed.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, April 22, 2020 12:54 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: RE: Preparation for HEVER COVID-19 call

So you are just going to select what you need out of today's call and have your staff put them in the NIH format? Just want to be clear.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, April 22, 2020 12:29 PM
To: Wood, Gretchen (NIH/OD) [E] [b6]
Cc: McManus, Ayanna (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
[b6] Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
Subject: RE: Preparation for HEVER COVID-19 call

Yes, I will use slides, but they won't be ready until tomorrow.

From: Wood, Gretchen (NIH/OD) [E] [b6]
Sent: Wednesday, April 22, 2020 12:01 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: McManus, Ayanna (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
[b6]
Subject: Re: Preparation for HEVER COVID-19 call

Thanks, Francis. The HEVER team wants to know if you intend to use slides or have any background materials to share for that meeting. They would like them today, if possible.

From: Francis Collins [b6]
Date: Wednesday, April 22, 2020 at 11:13 AM
To: Gretchen Wood [b6]
Cc: "McManus, Ayanna (NIH/OD) [E] [b6]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6]
Subject: RE: Preparation for HEVER COVID-19 call

Yes, I am available and will have to skip the Response Team call on Friday.

From: Wood, Gretchen (NIH/OD) [E] [b6]

Sent: Wednesday, April 22, 2020 9:57 AM

To: Collins, Francis (NIH/OD) [E] [b6]

Cc: McManus, Ayanna (NIH/OD) [E] [b6]

Subject: FW: Preparation for HEVER COVID-19 call

Importance: High

Good morning, Francis,

Apologies for my confusion about this. Are you able to participate in this call starting at 7:30 AM on Friday? I thought I had seen another entry that had to do with a white paper last week. Appreciate your guidance.

From: "Giurdanella, Rosetta" [b6]

Date: Tuesday, April 21, 2020 at 10:09 AM

To: Gretchen Wood [b6], "McManus, Ayanna (NIH/OD) [E]" [b6]

Subject: FW: Preparation for HEVER COVID-19 call

Dear Gretchen/Ayanna,

I am following up on Morten's e-mail below regarding a HEVER COVID-19 meeting that is scheduled for Friday, April 24th at 7:30am EST. The meeting will take place with Mikael Dolsten, Morten Sogaard from Pfizer and with about 25 other pharmaceutical leaders. Can you please confirm that Dr. Collins is indeed available at that time. I will send an invitation and dial-in instructions shortly.

Thank you and regards,
Rosetta

Rosetta Giurdanella

Target Sciences | Worldwide R&D

Pfizer Inc | 235 E. 42nd St. | New York, NY 10017

[b6]

From: Sogaard, Morten [b6]

Sent: Monday, April 20, 2020 11:21 PM

To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Dolsten, Mikael [b6]; Dolsten, Mikael [b6]

[b6] Giurdanella, Rosetta [b6] Protasiewicz, Ann

[b6]
Subject: Preparation for HEVER COVID-19 call

Dear Francis,

I hope all is well.

I am writing to follow up on your conversation with Mikael about the upcoming HEVER COVID-19 meeting on Friday 7.30 a.m. EST.

APAR0000017423

The current thinking is that Mikael will kick off the meeting to set the stage and that you would then give an overview of the ACTIV initiative - 15 minutes or so. This would be followed by a discussion with the broader group on actions that could be taken to align COVID-19 collaborative initiatives.

Andy Plump will be able to join for the first 30 minutes and is interested in contributing one or two slides on his initiative, which we could take either before your presentation or after.

We would like to ideally circulate slides by the end of Wednesday and were hoping that this might be acceptable, otherwise please let us know.

Because of the set up (WebEx) we would like to make sure that colleagues who have technical difficulties with the WebEx will be able to dial in and see the pre-circulated slides.

I cc Ayanna as well as Rosetta and Ann at our end for help with follow up.

Best Regards and Thank You, on behalf of Mikael and myself,
Morten

Morten Sogaard, Ph.D. | Vice President Emerging Science & Innovation, Head Target Sciences, Worldwide RD&M

Pfizer Inc 235 East 42nd Street, Office 235/6/40, New York, NY 10017 | Phone:

b6

| Mobile:

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b6

Phone:

b6

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 2/3/2021 3:22:31 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: ACTIV Daily Update 20210203.pptx

PS, Joe Menetski will join us for the first part of the meeting for a discussion on global linkages to the PROTECT program.

From: Wholley, David (FNIH) [T]
Sent: Tuesday, February 2, 2021 10:21 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Rutter, Joni (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]
Subject: ACTIV Daily Update 20210203.pptx

Please find attached the slides for tomorrow morning's ACTIV war room call, Wednesday February 3. Welcome, Joni Rutter!

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/14/2020 4:20:14 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel];

Subject: Canceled: Daily ACTIV Calls

Attachments: Untitled Attachment; Untitled Attachment; Canceled: Daily ACTIV Calls; Untitled Attachment

Location: Dial-in: [b6] Passcode: [b6]

Start: 8/6/2020 6:30:00 PM

End: 8/6/2020 7:00:00 PM

Show Time As: Free

Recurrence: Weekly
every Thursday from 2:30 PM to 3:00 PM

Required Attendees: Wholley, David, Collins, Francis (NIH/OD) [E], Tabak, Lawrence (NIH/OD) [E], Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: McManus, Ayanna (NIH/OD) [E], Wood, Gretchen (NIH/OD) [E], Simon, Dina (NIH/OD) [C]; Carver, Trea (NIH) [C];

Attendees: Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]

Cancelling Thursday war room calls

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

To: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel];

Attachments: ACTIV Daily Update 20200806_v3.pptx

Start: 8/6/2020 6:30:00 PM
End: 8/6/2020 7:00:00 PM

Recurrence: (none)

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David, Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Menetski, Joseph

Extending through August

Dial-in: [b6]
Passcode: [b6]

Dr. Tabak as Leader: [b6]

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; McManus, Ayanna
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]

Attachments: RE: ACTIV Daily Update 20200812.pptx; ACTIV Daily Update 20200813.pptx

Start: 8/13/2020 3:00:00 PM
End: 8/13/2020 3:30:00 PM
Show Time As: Busy

Recurrence: (none)

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Due to unavoidable conflict for Dr. Collins, we are changing call from 2:30 p.m. to 11 a.m. Thursday, August 13.

Dial-in: [b6]
Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 8/12/2020 6:56:53 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: ACTIV Daily Update 20200812.pptx

That was the tentative idea, but we need to discuss again in tomorrow's War Room.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 2:29 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

Well, we have not decided exactly, but I thought we were entertaining ACTIV for trials 1-4 and probably 5 (BET), "ACTIV-Associated Trials" for IVIG and Conv. Plasma efforts, and NIH Covid Trials for everything else.h

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 2:17 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

Hi David,

Sorry I missed this. What did we decide? ACTIV and NIH COVID Treatment Trials? ACTIV and ACTIV-Like Trials?

I will rename the BET trial as (ACTIV-5), include the IVIG (ACTIV-like 6 or ACTIV-6 study?), and rename the CP trials (ACTIV-like 7a; 7b; etc.?)

Thank you,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 8:55 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

I think you'd need to change the title from "ACTIV" on the first slide as we discussed, and a key to explain the colors would be good, but agree with Jim this is a great summary.

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Wednesday, August 12, 2020 8:28 AM

To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]

Subject: RE: ACTIV Daily Update 20200812.pptx

Please see the attached working draft of the ACTIV grid.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]

Sent: Wednesday, August 12, 2020 7:17 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]

Subject: ACTIV Daily Update 20200812.pptx

For this morning's war room, Wednesday August 12. N.B. Maria may not be able to join.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 8/26/2020 8:15:52 PM
To: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabak]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabak]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]
Subject: Canceled: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 8/27/2020 4:00:00 AM

End: 8/28/2020 4:00:00 AM

Show Time As: Free

Recurrence: Weekly
 every Thursday from 2:30 PM to 3:00 PM

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Carver, Trea (NIH) [C];

Attendees: Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]

Note: Per Dr. Collins, there is no need for this call. I am cancelling per his request.

Extending through August

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]

Start: 9/3/2020 6:30:00 PM
End: 9/3/2020 7:00:00 PM
Show Time As: Free

Recurrence: (none)

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Cancelling Thursday war room calls

Dial-in: [b6]
Passcode: [b6]

Dr. Tabak as Leader: [b6]

Sent: 4/24/2020 12:09:28 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]
Subject: FW: A proposal to stop COVID-19 and reopen our schools and businesses

Thank

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, April 24, 2020 8:02 AM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Jorgenson, Lyric (NIH/OD) [E] [b6]
Subject: RE: A proposal to stop COVID-19 and reopen our schools and businesses

Thanks

From: Wolinetz, Carrie (NIH/OD) [E] [b6]
Sent: Friday, April 24, 2020 7:51 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Jorgenson, Lyric (NIH/OD) [E] [b6]
Subject: RE: A proposal to stop COVID-19 and reopen our schools and businesses

Thanks, David. Just FYI, there is a formal system run by our Executive Secretariat for assigning response to emails or correspondence that comes into Francis. It is not an OSP function. Cheers, Carrie

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and
Associate Director for Science Policy
Office of the Director
National Institutes of Health (NIH)

[b6]
<http://osp.od.nih.gov/>

Please follow on Twitter: @CWolinetzNIH



From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 23, 2020 10:28 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Wolinetz, Carrie (NIH/OD) [E] [b6]; Jorgenson, Lyric (NIH/OD) [E] [b6]
Subject: Re: A proposal to stop COVID-19 and reopen our schools and businesses

Thanks, David. I've seen this email — since it was sent directly to Francis.

I'm cc'ing Carrie and Lyric for awareness.

Thanks again,
Ashley

On Apr 23, 2020, at 9:51 PM, Wholley, David (FNIH) [T] [b6] wrote:

For logging with your other inquiries. As I have mentioned before, FNIH views formal group appeals to the NIH Director as an issue for NIH OSP to handle.

From: David Liu [b6]
Sent: Thursday, April 23, 2020 6:01 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Michael Rosbash [b6]; Ramnik Xavier [b6]; EDWARD SCOLNICK [b6]; Stuart Schreiber [b6]; Michael Z Lin [b6]; Ben Cravatt [b6]; Thomas Cahill [b6]; R. Scott Kemp [b6]
Subject: Re: A proposal to stop COVID-19 and reopen our schools and businesses

Dear Francis, Anthony, Cliff, Christopher, David, Maria, and Lawrence,

I hope you are all well. Attached is the updated set of four proposals on:

- 1) Rapid repurposing of antiviral drugs to treat COVID-19;
- 2) Expedited development of neutralizing monoclonal antibodies to treat COVID-19;
- 3) Rapid COVID-19 vaccine development;
- 4) Risk-reduced ways to reopen schools and businesses, and the healthcare system changes that are needed to enable them.

We hope you find these updated proposals useful, and would be happy to engage in any way that could be helpful.

Sincerely yours,

Ben Cravatt (Scripps), Lynn Goldman (GWU), Akiko Iwasaki (Yale), Scott Kemp (MIT), Michael Lin (Stanford), David Liu (Harvard/Broad), Michael Rosbash (Brandeis), Stuart Schreiber (Harvard/Broad), Ed Scolnick (Broad), Jonathan Simons (PCF), and Ramnik Xavier (MGH/Broad)

David R. Liu
Richard Merkin Professor and Director of the Merkin Institute
of Transformative Technologies in Healthcare
Director of the Chemical Biology and Therapeutic Sciences Program
Core Institute Member and Vice-Chair of the Faculty, Broad Institute
Investigator, Howard Hughes Medical Institute
Thomas Dudley Cabot Professor of the Natural Sciences
and Professor of Chemistry & Chemical Biology, Harvard University
75 Ames Street
Cambridge, MA 02142

On Apr 19, 2020, at 8:48 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Dear David et al.,

Thanks for forwarding this very thoughtful document, which presents a series of important recommendations – most of which I agree with. I don't know if you saw Friday's announcement (attached) of the new public private partnership called ACTIV (for Accelerating COVID-19 Therapeutic Interventions and Vaccines), but it has taken on most of the points you raise in sections 1 – 3 of your letter. I share your hopes that remdesivir will show benefit, and the current large NIH-sponsored RCT has completed enrollment and should reveal results in about a month. But of course we want to test multiple other interventions – both small molecules and antibody-based therapies, so we need our trial system to be optimized like never before. I will share your letter with the leaders of ACTIV, who are working with unprecedented speed to prioritize the next set of therapeutic candidates as well as pushing vaccine development programs to adopt exceptionally creative trial designs to test safety and efficacy (with full engagement by FDA).

Best regards, Francis

From: David Liu [b6]
Sent: Sunday, April 19, 2020 5:20 PM
To: OD Labc (NIH/OD) [b6]; Collins, Francis (NIH/OD) [E]
Cc: Michael Rosbash [b6]; Ramnik Xavier [b6]; EDWARD SCOLNICK [b6] Stuart Schreiber [b6]; Michael Z Lin [b6]; Ben Cravatt [b6]
Subject: A proposal to stop COVID-19 and reopen our schools and businesses

Dear Francis,

I hope you are well.

I write on behalf of a group of citizen-scientists, most or all of whom you know. Motivated solely by our desire to help defeat the serious threat our nation and the world now faces, we wrote a set of four actionable, non-partisan proposals (attached) to produce safe and effective COVID-19 therapeutics and vaccines in the shortest possible timeframe, and to reopen our society in a manner that reduces the risk of future COVID-19 outbreaks.

We hope you find these ideas interesting, and might be willing to share this set of proposals with Dr. Tony Fauci, along with our willingness to discuss any part of the proposals with him if we can be helpful. We understand from our efforts to contact Dr. Fauci through email routes that his standard inbox may be too overwhelmed for our proposal to reach him.

The four proposals attached describe: (1) How to rapidly repurpose an antiviral drug to treat COVID-19 patients; (2) How to expedite the development of human antibody drugs to treat patients and to provide short-term protection for healthy individuals; (3) How to develop COVID-19 vaccines on an expedited time scale; and (4) How to reopen our

businesses and schools in a manner that reduces the risk of future outbreaks and deaths.

Thank you for any help or thoughts you might be able to provide.

Sincerely yours,

Ben Cravatt (Scripps), Lynn Goldman (GWU), Akiko Iwasaki (Yale), Scott Kemp (MIT), Michael Lin (Stanford), David Liu (Harvard/Broad), Michael Rosbash (Brandeis), Stuart Schreiber (Harvard/Broad), Ed Scolnick (Broad), Jonathan Simons (PCF), and Ramnik Xavier (MGH/Broad)

David R. Liu
Richard Merkin Professor and Director of the Merkin Institute
of Transformative Technologies in Healthcare
Director of the Chemical Biology and Therapeutic Sciences Program
Core Institute Member and Vice-Chair of the Faculty, Broad Institute
Investigator, Howard Hughes Medical Institute
Thomas Dudley Cabot Professor of the Natural Sciences
and Professor of Chemistry & Chemical Biology, Harvard University
75 Ames Street
Cambridge, MA 02142

<NIH_ACTIV_Release_041720.docx>

<Scientists_to_Stop_COVID19_2020_04_23_FINAL.pdf>

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/31/2020 12:45:13 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]

Subject: Canceled: Standing ACTIV-3 Site Investigators Meeting
Attachments: Standing ACTIV-3 Site Investigators Meeting; Untitled Attachment; Untitled Attachment
Location: <https://fnih.zoom.us> **b6**

Start: 7/29/2020 2:00:00 PM
End: 7/29/2020 3:00:00 PM
Show Time As: Free

Recurrence: Weekly
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: Mamta Jain; Jens Lundgren; Neaton, Jim; Harrigan, Rachel (HHS/IOS); Higgs, Elizabeth (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E]; Samuel Brown; **b6**
Harrington, Cristin A.; Kan, Virginia; Biswas, Kousick; Victoria Davey; Baracco Lira, Gio J (Miami VA); Baracco, Gio J, M.D.; Lichtenberger, Paola N. (Miami VA); Bhattacharya, Debika; Krah, Scott E.; Lim, Kokkheang; Williams, Allison E.; Ratliff, Whitney A.; Buck, Theresa A.; Taylor Thompson; **b6**
b6; Baker, Jason; Catherine Hough; Judith Anne Gallagher; Katharina Krapp; Daniel Dawson Murray; Sueiro, Melyssa (Miami VA); Peter Smith, M.D. (Thoracic Surgery); Christina Chang; Mark Polizzotto; Parker, CAPT Sheri (HHS/IOS); Christine Wenner; ID-Markowitz, Norman; Gardner, Edward M MD; Sanchez, Adriana; Kent P Hassett; Lilian Gonzalez; Andrew G Koustenis; Janice Evans; Wentworth, Debby; **b6** Ajay Nirula - Lilly; **b6** Patterson, Amy (NIH/NHLBI) [E]; Andrew Phillips; **b6** Birgit Grund; **b6** Lane, Cliff (NIH/NIAID) [E]; **b6**
b6; Eric Hughes; **b6**
b6; Judy Currier; **b6**; Reineck, Lora (NIH/NHLBI) [E]; Kozak, Marina (OS/ASPR/BARDA); Miller, Marissa A (NIH/NHLBI) [E]; **b6**
b6; Proshan, Michael (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Paul Klekotka - Lilly; Cavan, Reilly; Roger Paredes; Read, Sarah (NIH/NIAID) [E]; Shweta Sharma; **b6**
b6 Rosenberg, Yves (NIH/NHLBI) [E]; Davey, Victoria; **b6**; Aileen Ilaria; Charles T Benson; Robert Jan Benschop; Lei Shen; Jenny Y Chien; Emmanuel Chigutsa; Daniel A Peterson; Daisy G Hartman; Jamie L Stack; Kristina Southern Dinkel; Susan R Moriarty; Gourab Datta; Patricia L Brown-Augsburger; Denning, Eileen; Larson, Gregg; John Rule; Teitelbaum, Marc (NIH) [C]; Cahill, Kelly (NIH/NIAID) [E]; Mack, Michael J; Moquete, Ellen; Marks, Mary; Gupta, Lopa, O'sullivan, Karen; Vallee, David; Birgit Grund; **b6**
b6
b6 Badrock, Jonathan; Gregory, Adam; **b6**
b6 Fenton, Kathleen (NIH/NHLBI) [E]; Taddei-Peters, Wendy (NIH/NHLBI) [E]

Optional Attendees: Driver, Brian; Accardi, Evan; Prekker, Matthew; Mackedanz, Shari; Gonzalez, Luis A. (Miami VA); Washburn, Katrina B. (Miami VA); Ramos, Carol F. (Miami VA); Kathleen Lane, RN, BSN; Beth Hollister; Vidales, Elizabeth; Alyssa Hughes; Sturgill, Jamie; Beverly, Jennifer, Moss, Marc; Rebekah K. Peacock; Mehkri, Omar; Jenna Davis; Chang, Steven Y.; Valerie Aston; Gray, Christopher S; Roth, Megan; Dudley, Adam; Robart, Emily; Nick Johnson; Calfee, Carolyn; Romaine, Connie; Liu, Kathleen Dori; Sarah A Sterling; Jarrod Mosier; Rosseto, Elinita (BIDMC - Emergency Medicine); Hyzy, Robert (Bob); Rice, Todd; D. Clark Files; Duggal, Abhijit; Doernberg, Sarah; DiFiore, Sara; Parry, Blair Alden;

Thomas Mazzocco; Utsav Nandi; Agarwal, Trisha; Talmor, Daniel S (HMFP - Anesthesia); Higgins, Carrie; Dugar, Siddharth; Kozikowski, Lori-Ann; Bienstock, Karen (NIH/NHLBI) [E]; Akram Khan, Christine A. Lord; Sahoo, Debasis; Jens Ulrik Stæhr Jensen; Steingrub, Jay; De Souza, Lesley; Sandi, Marie; Exline, Matthew C;

b6; Lisbeth Jørgensen; Nicole Engen; RH-FP-CHIP-ACTIV3-INSIGHT014; Tierney, John (NIH/NIAID) [E]; Marie Helleberg; Cate Carey; Vjecha, Michael; Hudson, Fleur; Pett, Sarah; Bitten Aagaard; Charlotte Bjernved Nielsen; Eccard-Koons, Vanessa (NIH) [C]; Buehn, Molly (NIH) [C]; MacDonald, Leah (NIH) [C]; Ganapathy Gopalrathnam; Janelle A Sabo; Carlos O Garner - Lilly; Tonya L Combs; Lori J Stephens; Lau, Chuen-Yen (NIH/NIAID) [E]; Herpin, Betsey (NIH/NIAID) [E]; Barrett, Kevin (NIH/NIAID) [E]; Smolskis, Mary (NIH/NIAID) [E]; Engel, Theresa (NIH) [C]; Osborne, Cynthia (NIH) [C]; Simpson, Shelly (NIH) [C]; Vogel, Susan (NIH/NIAID) [E]; Grace, Beth (NIH/NIAID) [C]; Proffitt, Calvin (NIH) [C]; Hohn, Matt (NIH) [C]; b6; Pierson, Jerome (NIH/NIAID) [C]; Mock, Rebecca (NIH/NIAID) [E]; Segal Raim, Sharon (NIH) [E]; Miller, Tracey (NIH) [C]; Parrish, David (NIH/NIAID) [E]; Galcik, Michael (NIH) [C]; Dighero-Kemp, Bonnie (NIH/NIAID) [C]; Hensley, Lisa (NIH/NIAID) [E]; Chen, Helen Q.; Eileen Denning; Baseler, Beth (NIH) [C]; Norman Gerry; DuChene, Alain; Gary Collins; Marie Hoover; DeBoisblanc, Bennett; Kays, Kyle Richard; Huebinger, Ryan M; David Lye Chien Boon (NCID); Elsaid, Olivia; Dorte Sandbæk Høgsberg; Hayes, Sharon R. R.N. (BIDMC - Emergency Medicine); Park, Pauline; Bryce Robinson; Katja Bergenholtz; Jenny Wilson; Nadine DuChateau; Rebekah Garcia; Andrew Vekstein; John Franzone; Gottlieb, Robert L; Sandkovsky, Uriel S; Thomas Holand, M.D.; Holland, Amy; Rahul Nair; Bowdish, Michael; Eyad Almasri; Sher, Linda; Scott, James RN; Robinson, Caitlin; Douglas, Ivor S MD; Cohen, Mitchell MD; Dr Tatyana Der; Davey, Richard (NIH/NIAID) [E]; Van, John Nguyen; Hines-Munson, Casey Eileen; Dillon, Laura M. (HOU); Laurie Spiess; Hendey, Gregory; Katja Lisa Kanne; Dawn Hawkins East; Henrik Nielsen; Tomas Østergaard Jensen; Thomas Lars Benfield; Kristine Toft Petersen; Birgit Thorup Røge; Sebastian Leicht Von Huth; Mette Løkke; RH-FP-Epi-Demus; Huyen Cao; Kinzel, Emily; Berryman, Emily; Emily Ko; Jannik Helweg-Larsen

Dear All,

On behalf of the leadership of INSIGHT, PETAL, CTSN, ACTG and DCR/NIAID, you are kindly invited to join the weekly ACTIV-3 investigator meetings, taking place at Wednesdays @ 9am Minnesota time.

INSIGHT is collaborating with PETAL, CTSN, the US VA, ACTG and the division of clinical research (DCR) at NIAID on this project. The development of the master protocol has brought leadership of these four networks and that from DCR/NIAID together to function as one team.

The ambitious plan is to get the first patient included on the trial by the 31st of July. A list of sites in the US has been identified as Vanguard; additional sites will be registered in August, as pace of enrolment will increase then.

The focus of the first meeting is an introduction to the protocol, give an overview of the study design, and briefly review the site registration process. The chat function allows for ongoing dialogue, so please enter comments and questions there. We will try to address some of the input during the call.

Feel free to circulate this invitation to staff at sites that are dedicated to being engaged in ACTIV-3.

Join Zoom Meeting

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Sent: 4/23/2020 11:56:46 AM
To: Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]
Subject: RE: ACTIV Daily Call Thursday, April 30

Good morning,

Spm is fine.

Thank you,
Ashley

From: Carver, Trea (NIH) [C] [b6]
Sent: Thursday, April 23, 2020 7:53 AM
To: Simon, Dina (NIH/OD) [C] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Lagos, Enrique (NIH/NCATS) [E] [b6]; Sepulveda, Dorina (FNIH) [T] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: ACTIV Daily Call Thursday, April 30

Good Morning,

Dr. Lane is available.

--
Thank You,
Trea

Trea Carver [C]
Staff Assistant to the Director
Division of Clinical Research (DCR)
National Institute of Allergy and Infectious Diseases/NIH
Building 10CRC/Room 4-1479
Phone: [b6]
Cell: [b6]
Fax: 301-480-5560
Email: [b6]

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From: "Simon, Dina (NIH/OD) [C]" [b6]
Date: Wednesday, April 22, 2020 at 5:28 PM
To: "Melencio, Cheryl (FNIH) [T]" [b6], "Lagos, Enrique (NIH/NCATS) [E]"
[b6], "Carver, Trea (NIH) [C]" [b6], "Sepulveda, Dorina (FNIH) [T]"
"Burrus-Shaw, Cyndi (NIH/OD) [E]" [b6]
Cc: "Wood, Gretchen (NIH/OD) [E]" [b6], "McManus, Ayanna (NIH/OD) [E]"
[b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: Re: ACTIV Daily Call Thursday, April 30

All,

I can make Dr. Tabak available at 5:00 pm on April 30.

Dina

From: "Simon, Dina (NIH/OD) [C]" [b6]
Date: Wednesday, April 22, 2020 at 5:25 PM
To: "Melencio, Cheryl (FNIH) [T]" [b6], "Lagos, Enrique (NIH/NCATS) [E]"
[b6], "Carver, Trea (NIH) [C]" [b6], "Sepulveda, Dorina (FNIH) [T]"
"Burrus-Shaw, Cyndi (NIH/OD) [E]" [b6]
Cc: "Wood, Gretchen (NIH/OD) [E]" [b6], "McManus, Ayanna (NIH/OD) [E]"
[b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: Re: ACTIV Daily Call Thursday, April 30

Dr. Tabak is available at 5:15 pm.

Dina

From: "Melencio, Cheryl (FNIH) [T]" [b6]
Date: Wednesday, April 22, 2020 at 4:30 PM
To: "Lagos, Enrique (NIH/NCATS) [E]" [b6], "Carver, Trea (NIH) [C]"
[b6], "Sepulveda, Dorina (FNIH) [T]" [b6], "Burrus-Shaw, Cyndi (NIH/OD)
[E]" [b6], "Simon, Dina (NIH/OD) [C]" [b6]
Cc: "Wood, Gretchen (NIH/OD) [E]" [b6], "McManus, Ayanna (NIH/OD) [E]"
[b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: RE: ACTIV Daily Call Thursday, April 30

Hi again

Due to a conflict with the 10 – 10:30 time slot, could your executive be available at 5 p.m. Thursday, April 30 for this call?

Thank you.

Cheryl

APAR0000017543

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19 fnih.org/pandemic



From: Melencio, Cheryl (FNIH) [T]

Sent: Wednesday, April 22, 2020 2:46 PM

To: Lagos, Enrique (NIH/NCATS) [E] b6; Carver, Trea (NIH) [C] b6; Sepulveda, Dorina (FNIH) [T] b6; Burrus-Shaw, Cyndi (NIH/OD) [E] b6; Simon, Dina (NIH/OD) [C] b6

Cc: Wood, Gretchen (NIH/OD) [E] b6; McManus, Ayanna (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6

Subject: ACTIV Daily Call Thursday, April 30

Good afternoon,

Due to an ACTIV Working Group call scheduled from 2-3 Thursday afternoon, would your executive be available from 10:00 – 10:30 a.m. for the daily call in place of the 2:30-3:00 time?

Thank you

Cheryl

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19 fnih.org/pandemic



From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 1/28/2021 5:44:45 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Margaret Anderson [FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse [jmendelson@deloitte.com]; Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan [jwachtel@deloitte.com]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]
Subject: ACTIV Pre-call
Location: see webex below
Start: 2/16/2021 6:15:00 PM
End: 2/16/2021 6:45:00 PM
Show Time As: Tentative

Required Attendees: Wholley, David; Menetski, Joseph; Adam, Stacey (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Anderson, Margaret;

Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Santos, Michael (FNIH) [T]; Sorosa, Alex, Stratton, Ben; Tolman, Brett; Wachtel, Jonathan
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 8/12/2020 9:09:59 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3ced1fd96-sepulvedade]

Subject: Canceled: Daily ACTIV Call

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: Dial-in: [b6] Passcode: [b6]

Start: 9/10/2020 6:30:00 PM

End: 9/10/2020 7:00:00 PM

Show Time As: Free

Recurrence: Weekly
every Thursday from 2:30 PM to 3:00 PM

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E];

Attendees: Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Carver, Trea (NIH) [C];

Attendees: Lagos, Enrique (NIH/NCATS) [E]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Donna (FNIH) [T]

Extending to end of November

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]

CC: Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Start: 9/10/2020 6:30:00 PM
End: 9/10/2020 7:00:00 PM
Show Time As: Free

Recurrence: (none)

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]
Optional Attendees: Carver, Trea (NIH) [C]; Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]

Extending to end of November

Dial-in:
Passcode:

Dr. Tabak as Leader:

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]

CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Start: 10/1/2020 6:30:00 PM
End: 10/1/2020 7:00:00 PM
Show Time As: Free

Recurrence: (none)

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]

Extending to end of November

Dial-in: [b6]
Passcode: [b6]

Dr. Tabak as Leader: [b6]

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]

CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Start: 9/24/2020 6:30:00 PM
End: 9/24/2020 7:00:00 PM
Show Time As: Free

Recurrence: (none)

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]

Extending to end of November

Dial-in:
Passcode:

Dr. Tabak as Leader:

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]

CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Start: 9/17/2020 6:30:00 PM
End: 9/17/2020 7:00:00 PM
Show Time As: Free

Recurrence: (none)

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]

Extending to end of November

Dial-in: [b6]
Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 8/12/2020 9:01:48 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: Canceled: Daily ACTIV Call

Attachments: Canceled: Daily ACTIV Call; Canceled: Daily ACTIV Call; Canceled: Daily ACTIV Call; Untitled Attachment

Location: Dial-in: [b6] Passcode: [b6]

Start: 9/8/2020 12:00:00 PM

End: 9/8/2020 12:30:00 PM

Show Time As: Free

Recurrence: Weekly
every Tuesday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E];

Optional Attendees: Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Carver, Trea (NIH) [C];

Optional Attendees: Lagos, Enrique (NIH/NCATS) [E]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Donna (FNIH) [T]

Extending to end of November

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

To: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

CC: Wood, Gretchen (NIH/OD) [E] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6]; Lagos, Enrique (NIH/NCATS) [E] [b6]; Hughes, Karen (NIH/OD) [E] [b6]; Sepulveda, Dorina (FNIH) [T] [b6]; Carver, Trea (NIH) [C] [b6]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: Canceled: Daily ACTIV Call

Start: 9/8/2020 12:00:00 PM

End: 9/8/2020 12:30:00 PM

Show Time As: Free

Recurrence: (none)

Required Attendees: Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Carver, Trea (NIH) [C]; Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Donna (FNIH) [T]

Extending to end of November

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

To: Anderson, James (NIH/OD) [E] [b6] Austin, Christopher (NIH/NCATS) [E]
[b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
[b6]; Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
[b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Sepulveda, Dorina (FNIH) [T] [b6]; Hughes, Karen (NIH/OD) [E] [b6]; Lagos,
Enrique (NIH/NCATS) [E] [b6]; Carver, Trea (NIH) [C] [b6]; Simon, Dina
(NIH/OD) [C] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Wood,
Gretchen (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs];
Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel]; Hughes, Karen (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: Canceled: Daily ACTIV Call

Start: 9/15/2020 12:00:00 PM

End: 9/15/2020 12:30:00 PM

Show Time As: Free

Recurrence: (none)

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E];
Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Extending to end of November

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

To: Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

CC: Sepulveda, Dorina (FNIH) [T] [b6]; Hughes, Karen (NIH/OD) [E] [b6]; Lagos, Enrique (NIH/NCATS) [E] [b6]; Carver, Trea (NIH) [C] [b6]; Simon, Dina (NIH/OD) [C] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: Canceled: Daily ACTIV Call

Start: 9/29/2020 12:00:00 PM

End: 9/29/2020 12:30:00 PM

Show Time As: Free

Recurrence: (none)

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Extending to end of November

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Start: 9/22/2020 12:00:00 PM
End: 9/22/2020 12:30:00 PM
Show Time As: Free

Recurrence: (none)

Required Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Extending to end of November

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 7/21/2020 2:29:33 PM
To: Alvarez, Rosa Maria [rosalvarez@deloitte.com]; [b6] Hewitt, Judith (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto,
Gregory [b6]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Stratton, Benjamin
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];
Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D
 [b6]; Jonson, Samantha (NIH/NCATS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]
Subject: ACTIV Preclinical - Data Portal Implementation
Attachments: Untitled Attachment
Location: <https://deloitte.zoom.us> [b6]
Start: 5/21/2020 1:00:00 PM
End: 5/21/2020 2:00:00 PM
Show Time As: Busy
Recurrence: (none)

Join Meeting

Password:

Phone one-tap:

b6

Join by Telephone

Dial:

Meeting ID

Password:

International numbers

b6

Zoom technology includes options for recording a meeting. If a meeting is being recorded, an audio and/or visual warning will be provided when you join a recorded meeting. A warning will also be provided if recording commences after you have joined the meeting. If you continue to participate in the meeting following these warnings, your participation will serve as your express consent to such recording.

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v.E.1

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 12/26/2020 10:54:05 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: ACTIV Call "War Room"
Location: Dial-in: 1-866-692-3582 Passcode: 2136309#

Start: 12/30/2020 1:00:00 PM
End: 12/30/2020 1:30:00 PM
Show Time As: Tentative

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Parker, Ashley (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Patterson, Amy (NIH/NHLBI) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Hughes, Karen (NIH/OD) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Carver, Trea (NIH) [C]

Dial-in: b6

Passcode: **b6**

Dr. Tabak as Leader: **b6**

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 1/13/2021 6:57:23 PM
To: Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfc346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina

[b6] Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr], Nasr, Hana
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: ACTIV-2/3 Trial Oversight Committee Meeting
Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210113.pdf
Location: [https://fnih.zoom.us/\[b6\]](https://fnih.zoom.us/j/[b6])

Start: 1/13/2021 8:00:00 PM
End: 1/13/2021 9:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM
Required Attendees: Woodcock, Janet (FDA/CDER); Wholley, David (FNIH) [T]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6] Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Dear ACTIV-2/3 TOC Members,

Please find attached the slides for today's meeting.

Thanks,
Stacey

Join Zoom Meeting
[https://fnih.zoom.us/\[b6\]](https://fnih.zoom.us/j/[b6])

Meeting ID: [b6]
Passcode: [b6]
One tap mobile

[b6] US (Chicago)
US (New York)

Dial by your location
[b6] US (Chicago)
US (New York)
US (Washington D.C.)
US (Tacoma)
US (Houston)
US (San Jose)
US (San Jose)

Meeting ID: [b6]
Passcode: [b6]
Find your local number: [https://fnih.zoom.us/\[b6\]](https://fnih.zoom.us/j/[b6])

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 6/5/2020 2:21:52 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: FW: [Non-DoD Source] contacts

Francis, since BG Talley has not responded to you, and Mr. Phillips has been rather persistent, I asked Stacey to begin responding to him and coaxing him along the path we'd like him to follow...fyi

-----Original Message-----

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, June 4, 2020 8:41 PM
To: Phillips, L Revell CIV DTRA (USA) [b6]; Butterson, Joan [b6]; Read, Sarah (NIH/NIAID) [E] [b6]
Cc: Hone, David M (Dave) CIV DTRA J9 (USA) [b6]
Subject: RE: [Non-DoD Source] contacts

Dear Revell,

My sincerest apologies for the delay in response. We needed to have a few conversations within ACTIV before getting back to you.

While we aim to be transparent and cooperative in all things, we were wondering if it would be better to have DTRA join our efforts and work with us on our existing protocols, allowing DTRA then to use those protocols within their network(s).

The timing would be right because your team could help us prioritize the next round of candidates to ensure the highest quality candidates are selected for the master protocols. Giving you access to these drug and deploying them within the same protocols would ensure we are harmonized.

Please let us know if you would be open to considering this approach. We are also happy get a call together and discuss further if that would be helpful.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

-----Original Message-----

From: Phillips, L Revell CIV DTRA (USA) [b6]
Sent: Thursday, June 4, 2020 5:52 PM
To: Butterson, Joan [b6]; Adam, Stacey (FNIH) [T] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]
Cc: Hone, David M (Dave) CIV DTRA J9 (USA) [b6]
Subject: RE: [Non-DoD Source] contacts

Hi Stacey, Sarah, Eric, and Joan

I reached out earlier, but haven't heard back. DoD has been having email issues so I apologize in advance if I have missed something that may appear in a day or two. I did want to let you know that we have found the attached study. It is strongly representative of what we are thinking for our trial. More documentation is available online, but if you would like me to send over more information on that trial please let me know. If ACTIV has any additional guidance they would like to provide to improve our coordination with you, please let us know soon.

Respectfully,
Revell

-----Original Message-----

From: Phillips, L Revell CIV DTRA (USA)
Sent: Tuesday, June 2, 2020 4:27 PM
To: 'Butterton, Joan R' [b6]; Adam, Stacey (FNIH) [T] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]
Cc: Hone, David M (Dave) CIV DTRA J9 (USA) [b6]
Subject: RE: [Non-DoD Source] contacts

Joan,
Thank you for the introduction.

Sarah, Eric,

As Joan mentioned, I am with DTRA. We are looking to rapidly run an outpatient trial looking at repurposed drugs to treat newly infected COVID-19 patients. We are still working on determining exactly what the protocol will look like. I want to make sure we are coordinated with ACTIV to the extent possible. I would appreciate it if you could share info regarding your protocol design, end points, data base fields, etc. that you think would be relevant to our trial.

Thank you,
Revell

--
L. Revell Phillips PhD
Science and Technology Manager
Joint Science and Technology Office
Defense Threat Reduction Agency
[b6]

Please note - I have no authority to direct you in any way to alter your contractual obligations. If changes are desired, they must be issued in writing and signed by a contracting officer. You should take no action on any change unless and until you receive such a modification. If you ever feel I am directing you to do something not in your contract please let me know and we can discuss it with the contracting officer.

-----Original Message-----

From: Butterton, Joan R [b6]
Sent: Tuesday, June 2, 2020 3:26 PM
To: Phillips, L Revell CIV DTRA (USA) [b6]; Adam, Stacey (FNIH) [T]
[b6]; Read, Sarah (NIH/NIAID) [E] [b6]
Cc: Hone, David M (Dave) CIV DTRA J9 (USA) [b6]
Subject: RE: [Non-DoD Source] contacts

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Hi Stacey, Sarah, and Eric; with this email I would like to connect you with Revell Phillips and David Hone from DTRA, who have been considering the rapid conduct of clinical trials using repurposed therapeutics. Many of their thoughts touch on work that we have done in the ACTIV Therapeutics Clinical Working Group. Although Revell and David's group may be working independently, I think there are good learnings concerning endpoints and study design that would be helpful to their efforts.

Revell and David, for your information Sarah and Eric are the co-chairs of the Therapeutics Clinical Working Group, and Stacey coordinates all of our activities.

Thanks,
--Joan

Joan R. Butterton, M.D.
Associate Vice President, Clinical Research Infectious Diseases Section Head,
Antibacterials/Antifungals/CMV

Merck Research Laboratories
BMB 3-413
33 Avenue Louis Pasteur
Boston, MA 02115
T: [b6]
F: 617-992-2446

APAR0000005226

b6

Administrative Assistant:

Tina Butcher

T: b6

b6

-----Original Message-----

From: Phillips, L Revell CIV DTRA (USA)

b6

Sent: Tuesday, June 2, 2020 12:49 PM

To: Butterson, Joan R

b6

Cc: Hone, David M (Dave) CIV DTRA J9 (USA)

b6

Subject: RE: [Non-DoD Source] contacts

EXTERNAL EMAIL - Use caution with any links or file attachments.

Hi Joan,

Thank you for the call yesterday and the offer to put Dave and I in contact with the trial working group at ACTIV. We are interested in having insight into what they are doing, and making sure that where possible we align with the work they are doing.

I am specifically looking for information on their trial protocols and endpoints etc. especially as they pertain to trials for newly diagnosed, out-patient therapeutics.

Dave Hone and I would be the correct government POCs.

Respectfully,

Revell

--

L. Revell Phillips PhD

Science and Technology Manager

Joint Science and Technology Office

Defense Threat Reduction Agency

b6

Please note - I have no authority to direct you in any way to alter your contractual obligations. If changes are desired, they must be issued in writing and signed by a contracting officer. You should take no action on any change unless and until you receive such a modification. If you ever feel I am directing you to do something not in your contract please let me know and we can discuss it with the contracting officer.

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Caution-<http://www.merck.com/contact/contacts.html>) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.

APAR0000005226

From: Lane, Cliff (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2D7E368A3137473BBCE161547A82F2DE-CLANE]
Sent: 6/3/2020 10:04:06 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: [Non-DoD Source] contacts

They are from a different part of DoD - the Defense Threat Reduction Agency (DTRA) - than the activities overseen by BG Talley. It would be ideal to try and have them as part of ACTIV. They typically bring money and ideas to the table. They do not have their own operational capacity. They might carry out programs by giving money to the operations under BG Talley (or to non-DoD entities).

One suggestion would be to let BG Talley know of their outreach and suggest a dialogue between DTRA and Team 2.

Cliff

> On Jun 2, 2020, at 10:01 PM, Wholley, David (FNIH) [T] [b6] wrote:

>
> How to handle? Send them to BG Talley?

>
> -----Original Message-----

> From: Adam, Stacey (FNIH) [T] [b6]
> Sent: Tuesday, June 2, 2020 9:23 PM
> To: Wholley, David (FNIH) [T] [b6]
> Subject: FW: [Non-DoD Source] contacts
> Importance: High

>
> Hi David,

>
> I am torn what I should do with this.
> They are DoD, so I feel like I should just ask them to come join our efforts and not start their own master protocol.
> However, are these DoD folks the same as our DoD folks?

>
> If I don't invite them to join us, is it kosher for me to just give them our protocol? Not so much from a sharing perspective, but from a perspective that they might end up using some of the networks we are targeting.

>
> What is your counsel on this?

>
> Thanks,
> Stacey

>
> Stacey J. Adam, PhD
> Director, Cancer
> Research Partnerships
> Direct: [b6] | Mobile: [b6]

>
> -----Original Message-----

> From: Phillips, L Revell CIV DTRA (USA) [b6]
> Sent: Tuesday, June 2, 2020 4:27 PM
> To: Butterson, Joan [b6]; Adam, Stacey (FNIH) [T] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]
> Cc: Hone, David M (Dave) CIV DTRA JS (USA) [b6]
> Subject: RE: [Non-DoD Source] contacts

>
> Joan,
> Thank you for the introduction.

>
> Sarah, Eric,
>
> As Joan mentioned, I am with DTRA. We are looking to rapidly run an outpatient trial looking at repurposed drugs to treat newly infected COVID-19 patients. We are still working on determining exactly what the protocol will look like. I want to make sure we are coordinated with ACTIV to the extent possible. I would appreciate it if you could share info regarding your protocol design, end points, data base fields, etc. that you think would be relevant to our trial.
>
> Thank you,
> Revell
>
>
> --
> L. Revell Phillips PhD
> Science and Technology Manager
> Joint Science and Technology Office
> Defense Threat Reduction Agency
> [REDACTED] b6
>
> Please note - I have no authority to direct you in any way to alter your contractual obligations. If changes are desired, they must be issued in writing and signed by a contracting officer. You should take no action on any change unless and until you receive such a modification. If you ever feel I am directing you to do something not in your contract please let me know and we can discuss it with the contracting officer.
>
>
>
>
> -----Original Message-----
> From: Butterson, Joan R [REDACTED] b6
> Sent: Tuesday, June 2, 2020 3:26 PM
> To: Phillips, L Revell CIV DTRA (USA) [REDACTED] b6; Adam, Stacey (FNIH) [T]
> [REDACTED] b6; Read, Sarah (NIH/NIAID) [E] [REDACTED] b6
> Cc: Hone, David M (Dave) CIV DTRA J9 (USA) [REDACTED] b6
> Subject: RE: [Non-DoD Source] contacts
>
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>
>
>
>
> ----
>
> Hi Stacey, Sarah, and Eric; with this email I would like to connect you with Revell Phillips and David Hone from DTRA, who have been considering the rapid conduct of clinical trials using repurposed therapeutics. Many of their thoughts touch on work that we have done in the ACTIV Therapeutics Clinical Working Group. Although Revell and David's group may be working independently, I think there are good learnings concerning endpoints and study design that would be helpful to their efforts.
>
> Revell and David, for your information Sarah and Eric are the co-chairs of the Therapeutics Clinical Working Group, and Stacey coordinates all of our activities.
>
> Thanks,
> --Joan
>
> Joan R. Butterson, M.D.
> Associate Vice President, Clinical Research Infectious Diseases Section Head,
> Antibacterials/Antifungals/CMV
>
> Merck Research Laboratories
> BMB 3-413
> 33 Avenue Louis Pasteur
> Boston, MA 02115
> T: [REDACTED] b6
> F: 617-992-2446
> [REDACTED] b6
>
> Administrative Assistant:
> Tina Butcher
> T: [REDACTED] b6
> [REDACTED] b6
>
>
>
>

> -----Original Message-----

> From: Phillips, L Revell CIV DTRA (USA) [b6]
> Sent: Tuesday, June 2, 2020 12:49 PM
> To: Butterson, Joan R [b6]
> Cc: Hone, David M (Dave) CIV DTRA J9 (USA) [b6]
> Subject: RE: [Non-DoD Source] contacts

> EXTERNAL EMAIL - Use caution with any links or file attachments.

> Hi Joan,

> Thank you for the call yesterday and the offer to put Dave and I in contact with the trial working group at ACTIV. We are interested in having insight into what they are doing, and making sure that where possible we align with the work they are doing.

> I am specifically looking for information on their trial protocols and endpoints etc. especially as they pertain to trials for newly diagnosed, out-patient therapeutics.

> Dave Hone and I would be the correct government POCs.

> Respectfully,

> Revell

> --
> L. Revell Phillips PhD
> Science and Technology Manager
> Joint Science and Technology Office
> Defense Threat Reduction Agency

> [b6]

> Please note - I have no authority to direct you in any way to alter your contractual obligations. If changes are desired, they must be issued in writing and signed by a contracting officer. You should take no action on any change unless and until you receive such a modification. If you ever feel I am directing you to do something not in your contract please let me know and we can discuss it with the contracting officer.

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Sent: 6/1/2020 4:16:08 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: Phase 1 start of first monoclonal antibody against SARS-CoV-2
Attachments: PYAA Study of LY-CoV555 EMBARGO.pdf

Here we go....

From: Daniel Skovronsky [b6]
Sent: Sunday, May 31, 2020 10:30 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Phase 1 start of first monoclonal antibody against SARS-CoV-2

Francis,

Tomorrow morning we'll be announcing our phase 1 trial which started dosing patients May 29th. We wouldn't have been able to get to this point at all if not for the great partnership and support from NIAID. Specifically John Mascola, Barney Graham and the VRC team have been a huge help. NIAID has been a beacon of light in a difficult time.

I mentioned to you before that when you spoke (and sang) at my medical school graduation (UPenn, back in the human genome project days) you had already made a huge impression on me. Now watching you leading the fight on covid19, I am once again grateful for your leadership on a project of national importance. You are making an incredible difference in the fight against covid19, and I look forward to continued collaboration through ACTIV and ACT. We're working closely with the teams from ACTG and HPTN that have been repurposed for fighting covid19 and have partnered on protocols for treatment and prevention, both of which should be able to start this month. Please don't hesitate to ask if there is anything I or Lilly can do to help you and the NIH. We stand ready to help you in any way we can.

Warm regards,
Dan

Daniel Skovronsky MD PhD
President Lilly Research Laboratories
Chief Scientific Officer
Eli Lilly and Company

[b6]

APAR0000005254

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/30/2020 5:30:48 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6] LaVange, Lisa M [b6] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6] Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Jens Lundgren [b6]
CC: Demarcus [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q. [q ngchen@deloitte.com]; Sa athin, Carla [b6]
Subject: Follow-up to ACTIV mAb Steering Committee Meeting
Attachments: ACTIV_Therapeutics-Clinical_Agent Prioritization_mAb Steering Committee_Meeting Minutes_20200529.pdf

Dear mAb Steering Committee,

Thank you all for a very productive meeting yesterday. As always, your input is very helpful for the trial teams. Please find attached the notes from yesterday's meeting and action items, in document and below. Please take note of any action items that apply for you.

Looking forward to working with you more next week.

Thanks,
 Stacey

Action Items

	Information	POC
1	Share the document outlining the safety data requirements prior to entering Phase II of ACTIV-2	Peter Stein / John Farley
2	Establish a trial oversight committee for the ACTIV trials and develop a charter to document the decision-making process	Stacey Adam / Janet Woodcock

- 3 Share ACTIV-2 and ACTIV-3 synopses with the mAb Steering Committee once available
- 4 Let Stacey Adam know if you would like to stay on as part of the Trial Oversight Committee for ACTIV-2 and/or ACTIV-3

Stacey Adam

mAb Steering Committee

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/29/2020 3:41:27 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q. [qingchen@deloitte.com]; Salathin, Carla [b6]
Subject: Materials for ACTIV mAb Steering Committee Meeting
Attachments: ACTIV_TX-Clinical_mAb Steering Committee Meeting_20200529.pdf

Dear mAb Steering Committee,

Please find attached the proposed agenda and slides for tomorrow. Please let us know if we need to add anything else to the agenda.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/28/2020 7:29:37 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: patient numbers for ACTIV-1 immunomodulators trial

Hi Francis:

ACTIV-1 is estimated at ~2000 patients.

The budget that was figured out with input from NIAID over last weekend and submitted to OWS was ~\$70M.

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

b6

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/28/2020 6:19:56 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: FW: NHLBI Follow Up

FYI

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, May 28, 2020 2:17 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: FW: NHLBI Follow Up

Hi David,

FYI. We will need to talk about just hiring a CRO to run the ACTIV-1 trial if we don't want delays.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Patterson, Amy (NIH/NHLBI) [E] [b6]
Sent: Thursday, May 28, 2020 12:11 PM
To: Read, Sarah (NIH/NIAID) [E] [b6] >; Adam, Stacey (FNIH) [T] [b6]
Cc: Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Hoots, W. Keith (NIH/NHLBI) [E] [b6]
Subject: NHLBI Follow Up

Hi Sarah and Stacey,

As promised, we wanted to follow up with you regarding NHLBI's collaborative engagement with ACTIV. We've had the opportunity to discuss among NHLBI leadership and are very enthusiastic about partnering on the Phase II mAb inpatient and, if possible, outpatient trials. We view this as a natural fit with our current workstream in the passive immunity space, given our trials of CP and hyperimmune globulin.

With regard to our participation in the mAb trials, we anticipate engaging relevant experts from the NHLBI network of networks including perhaps PETAL and one or two other inpatient networks for ACTIV-3 and outpatient networks for ACTIV-2 to help expedite study completion. We are also happy to provide domain expert leads to assist in finalization of the MP as appropriate – so please let us know the next steps for further engagement.

As you know, we are now in the process of standing up the network of networks and awarding the Administrative Coordinating Center, completing our initial trials, and developing and launching the anticoagulation platform studies. For these reasons, and after careful consideration, we would not be able to take on the initial round for ACTIV-1 immunomodulators but are willing (capacity permitting) to potentially participate in the development of subsequent waves.

Happy to discuss further.

Regards,

Amy P. Patterson, M.D.
Chief Science Advisor and
Director of Scientific Research Programs, Policy, and Strategic Initiatives
National Heart, Lung, and Blood Institute
National Institutes of Health

Bldg. 31, Room 5A48
Bethesda, MD 20892

b6

From: Currier, Judith, M.D. [b6]
Sent: 5/22/2020 2:42:28 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: Scheduling an ACTIV TX-Clinical Master Protocol mAbs Steering Committee Tomorrow

1-2 Pm ET works for me.

Judy

From: "Adam, Stacey (FNIH) [T]" [b6]
Date: Thursday, May 21, 2020 at 7:11 PM
To: "Higgs, Elizabeth (NIH/NIAID) [E]" [b6], "Bozzette, Sam (NIH/NCATS) [E]" [b6], "Butterton, Joan" [b6], JUDITH CURRIER [b6], Eric Hughes [b6], "LaVange, Lisa M" [b6], "Read, Sarah - DAIDS" [b6], Karen Lynn Price [b6], "Woodcock, Janet (FDA/CDER)" [b6], "Stein, Peter (FDA/CDER)" [b6], Carlos O Garner [b6], "Bugin, Kevin (FDA/CDER)" [b6], "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" [b6]
Cc: Demarcus [b6], "Tountas, Karen (FNIH) [T]" [b6], "Wachtel, Jonathan" <jwachtel@deloitte.com>, Elizabeth Kim <elkim@deloitte.com>, "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: Scheduling an ACTIV TX-Clinical Master Protocol mAbs Steering Committee Tomorrow

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Hi Everyone,

For those that I have heard from, the best time for this meeting seems to be right before our larger master protocol meeting.

Would everyone on this group be able to make a 1-2pm ET meeting tomorrow to discuss the inpatient networks and to help the outpatient team address outstanding issues?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, May 21, 2020 3:53 PM
Subject: RE: Follow-up ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review

Hi Sam,

We can definitely discuss though there maybe some sensitivities in reaching out to the investigators. We will definitely need to have NHLBI as part of the conversation.

To the group,

I have responses from both NHLBI and INSIGHT on our questions. I will compile them in to one email for your review. However, I think it might be good if we were to get together tomorrow to discuss this and to discuss a few outstanding questions for the ACTIV-2 trial.

Please let me know if you would be available tomorrow for a meeting and we will work to get quorum.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/22/2020 2:10:59 AM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]
CC: Demarcus [demarcus@email.unc.edu]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Scheduling an ACTIV TX-Clinical Master Protocol mAbs Steering Committee Tomorrow

Hi Everyone,

For those that I have heard from, the best time for this meeting seems to be right before our larger master protocol meeting.

Would everyone on this group be able to make a 1-2pm ET meeting tomorrow to discuss the inpatient networks and to help the outpatient team address outstanding issues?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, May 21, 2020 3:53 PM
Subject: RE: Follow-up ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review

Hi Sam,

We can definitely discuss though there maybe some sensitivities in reaching out to the investigators. We will definitely need to have NHLBI as part of the conversation.

To the group,

I have responses from both NHLBI and INSIGHT on our questions. I will compile them in to one email for your review. However, I think it might be good if we were to get together tomorrow to discuss this and to discuss a few outstanding questions for the ACTIV-2 trial.

Please let me know if you would be available tomorrow for a meeting and we will work to get quorum.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/21/2020 10:55:16 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: Urgent Asks about ACTIV mAb Protocols/Studies

So, we're going to need your help on how to answer #4, Francis.

From: Bugin, Kevin [b6]
Sent: Thursday, May 21, 2020 6:23 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Woodcock, Janet (FDA/CDER) [b6] Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Urgent Asks about ACTIV mAb Protocols/Studies

Hi David,
Please see below:

1. Yes
2. Both
3. CRO portions only. But let us know if NIH needs funding beyond that. We can put in separate asks for that. I know there is still much to be TBC about even the CRO portions, because we may not need to cover the full scope of CRO services since some pieces may already be in place. We do not have to limit ourselves to one of the existing BARDA CROs, but that would be the most expedient path. Luckily I think there is a lot of overlap with the CROs I've heard ACTIV mention in the calls I've been on. Does ACTIV/NIH have preferred CROs? If you all have preferences we can include that in our selection criteria.
4. We had hoped to send out the RFI on Friday, so tomorrow should work. If it's earlier in the day that would be great!

Thanks,

Kevin

From: Wholley, David (FNIH) [T] [b6]
Date: May 21, 2020 at 5:33:49 PM EDT
To: Bugin, Kevin [b6], Adam, Stacey J (NIH) [b6]
Cc: Woodcock, Janet [b6]
Subject: RE: Urgent Asks about ACTIV mAb Protocols/Studies

Kevin:

Sure we'll help. A couple of questions just to make sure we are answering the right questions:

1. Your interest right now is solely in estimating the mAb protocols that ACTIV is working with you to get planned, not the immunomodulators, or anticoagulant trials that are also in the works, or the future denovo master protocol what would test other drugs, including antivirals. Is that right?

2. Assuming the answer to (1) is “yes,” are you wanting information that could help you estimate the cost of running just the outpatient mAbs master protocol? Or the inpatient protocol for mAb as well?
3. As you probably know, the ACTIV groups have been in dialogue with the NIAID ACTG network for the outpatient mAbs protocol and with either or both of the NIAID INSIGHT and NHLBI PETAL networks for the inpatient mAbs protocol. Both of these will likely need varying levels of help from a CRO to add sites and/or help with operational insights, while the NIH networks form the core and would hold the INDs (we think). Are you seeking to get funds to fund the entire trials including funding through all of these players? Or are you just asking for funding for what you think “the CRO portion” of these trials would be? And are you saying they have to be one of BARDA’s CROs to get funded?
4. To answer your question about the protocol synopsis for the outpatient mAbs protocol: no, the version you have is not the latest and likely not what you should use. There should be a better version I am told sometime later tomorrow: there are still some major design decisions that need to be ratified that could have a reasonably major effect on cost, including how many doses (1 or 2) will be used and whether a sophisticated Bayesian design or a simpler design is needed. Is that timing OK with you?

Please copy Stacey on all replies, thanks.

David

From: Bugin, Kevin [b6]
Sent: Thursday, May 21, 2020 2:18 PM
To: Wholley, David (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6]
Cc: Woodcock, Janet (FDA/CDER) [b6]
Subject: Urgent Asks about ACTIV mAb Protocols/Studies
Importance: High

Hi David and Stacey,

I hope your week is going well. I’m definitely seeing a lot of activity! Sadly, we might need to add to your load.

Dr. Woodcock has just been asked to provide near immediate input (i.e., by this weekend) into the development of a budget for the Therapeutics activities that are part of Operation Warp Speed. As you know, we intend to collaborate with you and ACTIV for the two mAb master protocols for outpatient and inpatient. While ACTIV and NIH will likely fund much of that work, we expect Operation Warp Speed via BARDA will help augment and act as a force multiplier related to the CRO and networks/sites. While we only have a protocol synopsis at this point for outpatient we believe we can use that to some extent to base estimates for size/complexity of the two studies which we can use to estimate CRO costs. In addition, any information that has started to come through about the networks/sites that ACTIV wants to leverage—that I understand Mike K’s group is pulling together—will be very helpful. Depending on where we are targeting sites, we can check BARDA’s portfolio and our Clinical Trial Data Lake to identify potential concerning overlaps and gaps. Not to second guess anything, but to help us guesstimate additional CRO/Site/Network demands.

All this to say, **can you confirm that the attached is the most current outpatient synopsis? Are you OK if we use this to inform BARDA’s development of an RFI to CROs to get some quick bids/estimates? Also, do you know the timeline for Mike’s working group for updating their inventory?** If this isn’t this week, no problem. We’re not entirely sure how much that will inform budget ask at this point since there is much to still work through. But, wanted to ask.

Thanks,
Kevin

From: Woodcock, Janet [REDACTED] b6
Sent: 5/21/2020 10:48:51 PM
To: Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [REDACTED] b6; LaVange, Lisa M [REDACTED] b6; Karen Lynn Price [REDACTED] b6; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Stein, Peter (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [REDACTED] b6; Bugin, Kevin (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]
CC: Demarcus [REDACTED] b6; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Compiled Responses from NHLBI and INSIGHT to our questions

Agree. jw

From: Read, Sarah (NIH/NIAID) [E] [REDACTED] b6
Sent: Thursday, May 21, 2020 6:31 PM
To: Adam, Stacey J (NIH) [REDACTED] b6; Bozzette, Sam A (NIH) [REDACTED] b6; Butterson, Joan [REDACTED] b6; Judy Currier [REDACTED] b6; Eric Hughes [REDACTED] b6; LaVange, Lisa M [REDACTED] b6; Karen Lynn Price [REDACTED] b6; Higgs, Elizabeth S (NIH) [REDACTED] b6; Woodcock, Janet [REDACTED] b6; Stein, Peter [REDACTED] b6; Carlos O Garner [REDACTED] b6; Bugin, Kevin [REDACTED] b6; Marks, Gilbert L (OS) [REDACTED] b6
Cc: Demarcus [REDACTED] b6; Tountas, Karen H (NIH) [REDACTED] b6; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley S (NIH) [REDACTED] b6
Subject: RE: Compiled Responses from NHLBI and INSIGHT to our questions

I'm certainly biased as I have worked with INSIGHT in the past on a large, multinational HIV treatment trial and I am not nearly as familiar with NHLBI's networks, but INSIGHT's responses below further bolster my confidence in that network to be able to efficiently implement this trial. Furthermore, with Libby's help, we were able to confirm that if INSIGHT is selected, NIAID will be able to hold the IND for both protocols (DAIDS and DCR) which may also provide efficiencies.

Sarah

From: Adam, Stacey (FNIH) [T] [REDACTED] b6
Sent: Thursday, May 21, 2020 4:05 PM
To: Bozzette, Sam (NIH/NCATS) [E] [REDACTED] b6; Butterson, Joan [REDACTED] b6; Judy Currier [REDACTED] b6; Eric Hughes [REDACTED] b6; LaVange, Lisa M [REDACTED] b6

[b6]; Read, Sarah (NIH/NIAID) [E]; [b6]; Karen Lynn Price
[b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Woodcock, Janet (FDA/CDER)
[b6]; Stein, Peter (FDA/CDER) [b6]; Carlos O Garner
[b6]; Bugin, Kevin (FDA/CDER) [b6]; Marks, Gilbert (OS/ASPR/BARDA)
(CTR) [b6]
Cc: Demarcus [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan
<jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Compiled Responses from NHLBI and INSIGHT to our questions

Dear ACTIV TX-Clinical mAb Steering Committee,

Please find below the responses to the additional questions that we had for NHLBI and INSIGHT. Please review and let the group know if you have any thoughts.

Thanks,
Stacey

NHLBI

Thanks for the f/up. Answers below in red. Bottom line is we are ready to go. Jim

Just to double check, even though we know you mentioned willingness on the phone, would you be willing to work as a partner to INSIGHT if they were selected as the lead network? If so, would you still have interest in participating in the drafting of the protocol? PETAL, as part of the NHLBI network of networks, would very much prefer to lead the master protocol and work closely with INSIGHT. However, if INSIGHT is selected as the lead network, then PETAL and NHLBI COVID-19 ACC would be willing to partner with them and would want a significant role in the development of the protocol.

The ACTIV team noted that NHLBI does have a number of ongoing activities and plans, so they are curious if the group will be able to make ACTIV3 their highest priority for the near-term since it is a very high priority of ACTIV leadership? Yes, this would be their highest priority.

Do you have a sense of what your true net unused capacity/capability of your network, DCC, and of the operations teams are given the other trials you have ongoing? PETAL anticipates completing ORCHID enrollment in early June and is ready to start working on the mAb protocol now.

Would NHLBI have any interest or ability to hold the IND for this study, if selected as the lead, even though we understand this is not your usual procedure? Yes.

INSIGHT

Before responding to your questions, we would like to reiterate that our infectious disease network is ideally suited to both lead the development of the master protocol for evaluating neutralizing mAbs against SAR-CoV-2 and to carry out the trials of these drugs in a timely way. Our experience conducting HIVIG trials in influenza and planning two protocols of HIVIG for COVID-19, treatments with similar immune response mechanisms as the mAbs, are very relevant to the planning and conduct of mAbs trials. The global reach of our network, and the coordinating center structure we have, will allow us to target sites for participation where the epidemic is strongest and to complete the trials quickly.

Below are responses to your questions in bold.

Just to double check, even though we know you mentioned willingness on the phone, would you be willing to work as a partner to NHLBI if they were selected as the lead network if they are not the lead? If so, would you still have interest in participating in the drafting of the protocol?

The nature of network partnerships on trials of COVID-19 is evolving. Depending on how the partnership is proposed, we would be happy to consider this. As partners we would want to have a significant role in protocol development, the data collections plan, and how the trials were to be implemented.

To us, it would be far more logical for NHBLI networks to collaborate with us (an infectious disease network) as the lead network on trials of treatments aimed at the virus that causes COVID-19, and for us to collaborate with NHLBI, as the lead network on trials of anticoagulants aimed at preventing thrombotic events.

The ACTIV team noted that INSIGHT does have a number of ongoing activities, so they are curious if INSIGHT will be able to make ACTIV3 their highest priority for the near-term since it is a very high priority of ACTIV leadership?

We are able to give the mAbs master protocol for inpatients (assume this is ACTIV3) the highest priority in our network – both the master protocol development and the global implementation of the trial. We are nearing completion of the designs of the two HIVIG trials – one of these trials is for outpatients and the other is a relatively small inpatient trial due to the availability of HIVIG. It will only involve approximately 60 sites. The ACTT2 trial, in which EU and UK sites are participating, will be over in an estimated 6 weeks. If we are chosen to lead this effort, we would consider not participating in ACTT3, if there were a possibility of the mAbs trials competing for enrollment at EU and UK sites.

Also, as noted above, we are a global network with sites in South America, Asia and Africa, and these sites are not participating in the ACCT trial.

Do you have a sense of what your true net unused capacity/capability of your network, DCC, and of the operations team is?

There is considerable untapped capacity in this network and in the organizations involved in the leadership of this network (U of M and the ICCs). For example, we are working with about 300 sites. In all of these sites there are experienced infectious disease specialists. Our strong infectious disease expertise is critical for the design of the master protocol and for the implementation of the mAbs interventions. We are also discussing collaborations with the VA. This is another large, untapped resource that will further enhance our capabilities.

With respect to DCCs, we have already reached out to other statisticians with experience in master protocols, seamless phase 2/3 studies, and adaptive designs of the nature you described to us. For the development of the master protocol and for advice on the implementation of such protocols, Max Parmer at UCL (MRC Unit), and Joe Koopmeiners, Thomas Murray, and David Vock at the University of Minnesota have already agreed to work closely with the team of biostatisticians now working on INSIGHT COVID-19 studies (Drs. Abdel Babiker, Birgit Grund, Andrew Phillips, Cavan Reilly, and Jim Neaton). They will be supported by a strong team of MS-level statisticians.

With respect to operations, our four international coordinating centers, and our site coordinating centers in each country, can be scaled up to provide additional support for the conduct of the mAbs trials. This was the intent of our distributed organization for conducting infectious disease trials.

Would you work with a CRO if we needed to expand the capacity of your network or logistical resources (data monitoring, etc.)?

We would certainly consider this. As mentioned on our telephone call with you, we think a CRO could provide assistance with the collection of site registration documents for trial master files. While we already have substantial monitoring capabilities, a CRO could also help with monitoring in some regions. In addition, a CRO could provide assistance with auditing of regulatory submissions.

We anticipate that the ACTIV group will play a key role in establishing how companies providing treatments will collaborate with the network, e.g., with clinical trial and confidentiality agreements. We also assume that, based on past experience, NIH will hold the IND for the drugs studied and they will likely TORO some responsibilities to us. If this is not the case, a CRO could help support those activities.

Thank you for the opportunity to address these clarification questions. Please let us know if you have additional questions. We look forward to working with ACTIV.

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct. [b6] | Mobile. [b6]

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/21/2020 9:34:56 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: Urgent Asks about ACTIV mAb Protocols/Studies

fyi

From: Wholley, David (FNIH) [T]
Sent: Thursday, May 21, 2020 5:34 PM
To: Bugin, Kevin [b6] Adam, Stacey (FNIH) [T] [b6]
Cc: Woodcock, Janet (FDA/CDER) [b6]
Subject: RE: Urgent Asks about ACTIV mAb Protocols/Studies

Kevin:

Sure we'll help. A couple of questions just to make sure we are answering the right questions:

- 1) Your interest right now is solely in estimating the mAb protocols that ACTIV is working with you to get planned, not the immunomodulators, or anticoagulant trials that are also in the works, or the future denovo master protocol what would test other drugs, including antivirals. Is that right?
- 2) Assuming the answer to (1) is "yes," are you wanting information that could help you estimate the cost of running just the outpatient mAbs master protocol? Or the inpatient protocol for mAb as well?
- 3) As you probably know, the ACTIV groups have been in dialogue with the NIAID ACTG network for the outpatient mAbs protocol and with either or both of the NIAID INSIGHT and NHLBI PETAL networks for the inpatient mAbs protocol. Both of these will likely need varying levels of help from a CRO to add sites and/or help with operational insights, while the NIH networks form the core and would hold the INDs (we think). Are you seeking to get funds to fund the entire trials including funding through all of these players? Or are you just asking for funding for what you think "the CRO portion" of these trials would be? And are you saying they have to be one of BARDA's CROs to get funded?
- 4) To answer your question about the protocol synopsis for the outpatient mAbs protocol: no, the version you have is not the latest and likely not what you should use. There should be a better version I am told sometime later tomorrow: there are still some major design decisions that need to be ratified that could have a reasonably major effect on cost, including how many doses (1 or 2) will be used and whether a sophisticated Bayesian design or a simpler design is needed. Is that timing OK with you?

Please copy Stacey on all replies, thanks.

David

From: Bugin, Kevin [b6]
Sent: Thursday, May 21, 2020 2:18 PM
To: Wholley, David (FNIH) [T] [b6] > Adam, Stacey (FNIH) [T] [b6]
Cc: Woodcock, Janet (FDA/CDER) [b6]
Subject: Urgent Asks about ACTIV mAb Protocols/Studies
Importance: High

Hi David and Stacey,

I hope your week is going well. I'm definitely seeing a lot of activity! Sadly, we might need to add to your load.

Dr. Woodcock has just been asked to provide near immediate input (i.e., by this weekend) into the development of a budget for the Therapeutics activities that are part of Operation Warp Speed. As you know, we intend to collaborate with you and ACTIV for the two mAb master protocols for outpatient and inpatient. While ACTIV and NIH will likely fund much of that work, we expect Operation Warp Speed via BARDA will help augment and act as a force multiplier related to the CRO and networks/sites. While we only have a protocol synopsis at this point for outpatient we believe we can use that to some extent to base estimates for size/complexity of the two studies which we can use to estimate CRO costs. In addition, any information that has started to come through about the networks/sites that ACTIV wants to leverage—that I understand Mike K's group is pulling together—will be very helpful. Depending on where we are targeting sites, we can check BARDA's portfolio and our Clinical Trial Data Lake to identify potential concerning overlaps and gaps. Not to second guess anything, but to help us guesstimate additional CRO/Site/Network demands.

All this to say, **can you confirm that the attached is the most current outpatient synopsis? Are you OK if we use this to inform BARDA's development of an RFI to CROs to get some quick bids/estimates? Also, do you know the timeline for Mike's working group for updating their inventory?** If this isn't this week, no problem. We're not entirely sure how much that will inform budget ask at this point since there is much to still work through. But, wanted to ask.

Thanks,
Kevin

From: Currier, Judith, M.D. [b6]
Sent: 5/21/2020 8:52:34 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: Follow-up ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review

I am available tomorrow ET at 8*-9 11, 12, 1 (we have a call at 2)
(8 is 5 am for me but okay if needed)
Judy

From: "Adam, Stacey (FNIH) [T]" [b6]
Date: Thursday, May 21, 2020 at 12:53 PM
To: "Bozzette, Sam (NIH/NCATS) [E]" [b6], "Butterton, Joan" [b6], JUDITH CURRIER [b6], Eric Hughes [b6], "LaVange, Lisa M" [b6], "Read, Sarah - DAIDS" [b6], Karen Lynn Price [b6], "Higgs, Elizabeth (NIH/NIAID) [E]" [b6], "Woodcock, Janet (FDA/CDER)" [b6], "Stein, Peter (FDA/CDER)" [b6], Carlos O Garner [b6], "Bugin, Kevin (FDA/CDER)" [b6], "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" [b6],
Cc: Demarcus [b6], "Tountas, Karen (FNIH) [T]" [b6], "Wachtel, Jonathan" <jwachtel@deloitte.com>, Elizabeth Kim <elkim@deloitte.com>, "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: RE: Follow-up ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review

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Hi Sam,

We can definitely discuss though there maybe some sensitivities in reaching out to the investigators. We will definitely need to have NHLBI as part of the conversation.

To the group,

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Please let me know if you would be available tomorrow for a meeting and we will work to get quorum.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

APAR0000005307

Direct: [b6] Mobile: [b6]

From: Bozzette, Sam (NIH/NCATS) [E] [b6]
Sent: Wednesday, May 20, 2020 11:28 PM
To: Adam, Stacey (FNIH) [T] [b6]; Butterson, Joan [b6]; Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Woodcock, Janet (FDA/CDER) [b6]; Stein, Peter (FDA/CDER) [b6]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]
Cc: [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Follow-up ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review

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Thanks
S

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Date: Wednesday, May 20, 2020 at 10:05:22 PM
To: "Bozzette, Sam (NIH/NCATS) [E]" [b6]; "Butterson, Joan" [b6]; "Judy Currier" [b6]; "Eric Hughes" [b6]; "LaVange, Lisa M" [b6]; "Read, Sarah (NIH/NIAID) [E]" [b6]; "Karen Lynn Price" [b6]; "Higgs, Elizabeth (NIH/NIAID) [E]" [b6]; "Woodcock, Janet (FDA/CDER)" [b6]; "Stein, Peter (FDA/CDER)" [b6]; "Carlos O Garner" [b6]; "Bugin, Kevin (FDA/CDER)" [b6]; "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" [b6]
Cc: "Demarcus" [b6]; "Tountas, Karen (FNIH) [T]" [b6]; "Wachtel, Jonathan" <jwachtel@deloitte.com>; "Elizabeth Kim" <elkim@deloitte.com>; "Parker, Ashley (NIH/OD) [E]" [b6]
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In addition, just for reference, I am reattaching the most current version of the synopsis. Please let us know if you have any further feedback on the document or the study design in general. The writing team did meet again to and got good guidance from the FDA and others. They will continue to progress on the document.

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Thanks,
Stacey

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From: Higgs, Elizabeth (NIH/NIAD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0601CA55A82841ABA16353B96CFF8CA9-EHIGGS]
Sent: 5/21/2020 8:32:30 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: Follow-up ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review

Stacey,
I have 9, 10, and 1 and an ACTIV meeting on for 2.
Thx
Libby

From: "Bozzette, Sam (NIH/NCATS) [E]" [b6]
Date: Thursday, May 21, 2020 at 3:57 PM
To: "Adam, Stacey (FNIH) [T]" [b6]; "Butterson, Joan" [b6]; Judy Currier [b6]; Eric Hughes [b6]; "LaVange, Lisa M" [b6]; "Read, Sarah (NIH/NIAD) [E]" [b6]; Karen Lynn Price [b6]; "Woodcock, Janet (FDA/CDER)" [b6]; "Stein, Peter (FDA/CDER)" [b6]; Carlos O Garner [b6]; "Bugin, Kevin (FDA/CDER)" [b6]; "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" [b6]
Cc: Demarcus [b6]; Karen Tountas [b6]; "Wachtel, Jonathan" <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: RE: Follow-up ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review

I can do 9, 11, or 1. And I have an invitation from you for 2 PM already

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, May 21, 2020 3:53 PM

To: Bozzette, Sam (NIH/NCATS) [E] [b6]; Butterton, Joan [b6] Judy
Currier [b6]; Eric Hughes [b6] LaVange, Lisa M
[b6] Read, Sarah (NIH/NIAID) [E] [b6] Karen Lynn Price
[b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6] Woodcock, Janet (FDA/CDER)
[b6]; Stein, Peter (FDA/CDER) [b6] Carlos O Garner
[b6] Bugin, Kevin (FDA/CDER) [b6] Marks, Gilbert (OS/ASPR/BARDA)
(CTR) [b6]
Cc: Demarcus [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan
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Research Partnerships
Direct. [b6] Mobile: [b6]

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Read, Sarah (NIH/NIAID) [E] [b6]; Karen Lynn Price [b6] Higgs, Elizabeth
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APAR0000005308



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/20/2020 4:02:30 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]
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Subject: Materials for ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review
Attachments: 5401 Protocol Synopsis 051920v3.docx

Dear ACTIV TX-Clinical Master Protocol mAbs Steering Committee,

Please find attached the synopsis of the outpatient protocol for review at our meeting today. This was assembled by the ACTG group based on our writing team conversations and then edited a bit by Lisa and Karen for the statistical sections.

This document is NOT ready to share beyond this group yet, but could be gotten ready in short turn if needed for the company summit, Janet. We will just need to know when that is.

Finally, we will be discussing the selection of the inpatient network for the companion protocol today.

Thanks,

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/15/2020 7:31:41 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: FW: Quick Updates on ACTIV Master Protocols

FYI for Monday call—the latest. TX-Clinical group still not quite sure ACTG will be best home network for outpatient mAbs, will require a bunch of additional sites via CRO or whatever, which we think they can get. We know they are not right for the inpatient piece.
Planning/outreach continues over the weekend. Going to let Janet know this as well, so you don't overpromise anything specific in this area on Monday.

David

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, May 15, 2020 3:15 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: Quick Updates on ACTIV Master Protocols

Hi David,

Just wanted to update you on the progress on the ACTIV Master Protocols being developed by the TX-Clinical WG.

1. ACTT-3 will now be referred to as ACTIV-1, as we are liking looking for an additional network to take this on as the main lead network. NIAID will still likely be sponsor for the IND. We will be working with the Clinical Trial Capacity WG to locate the new network.
2. For the two master protocols for SARS-CoV-2 master protocol mAbs, we still do not have a home network for these yet, but we do have multiple candidates we are evaluating and will be taking a vote on the outpatient network over the next 24 hours.

Thanks,
Stacey

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/12/2020 10:26:45 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: FW: Discuss ACTG Outpatient Trial Being Part of ACTIV

FYI

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Tuesday, May 12, 2020 5:55 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: FW: Discuss ACTG Outpatient Trial Being Part of ACTIV

FYI. Looks like we have traction with the ACTG group.
And yes, Peter Kim is the PO.

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Currier, Judith, M.D. [b6]
Sent: Tuesday, May 12, 2020 5:36 PM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Read, Sarah (NIH/NIAID) [E] [b6]; Eric Hughes [b6]
elkim@deloitte.com; Eron, Joe [b6]; Kim, Peter (NIH/NIAID) [E] [b6]
Subject: Re: Discuss ACTG Outpatient Trial Being Part of ACTIV

Stacey, Sarah and Eric,

This is great news. It would be good to have a quick discussion including Joe Eron (ACTG Co-Chair) and Peter Kim so we can understand how this would work, but overall we are enthusiastic. Happy to try to get on a call in the next day if possible. Joe and Peter are copied here to help with scheduling. We have had interest from several companies already and it would be great to coordinate.

Judy

APAR0000005428

From: "Adam, Stacey (FNIH) [T]" [b6]
Date: Tuesday, May 12, 2020 at 1:55 PM
To: JUDITH CURRIER [b6]
Cc: "Read, Sarah - DAIDS" [b6], Eric Hughes [b6],
"elkim@deloitte.com" <elkim@deloitte.com>
Subject: Discuss ACTG Outpatient Trial Being Part of ACTIV

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Hi Judy,

Thank you again for your group presenting yesterday. We felt the group was very impressed by the effort, enough so that the co-chairs and I wanted to reach out to see what your group's appetite would be to be considered for being an ACTIV master protocol. If you are interested in this idea, we would love to discuss with you and/or your group.

If you are interested, I will let you know that we will have to have the TX-Clinical WG vote on bringing this in as our first/primary outpatient master protocol, and we would then have to present to ACTIV Executive Committee. Also, I would imagine that the Master Protocol Subgroup might wish to offer some feedback on the protocol. Would you be amenable to going through this process? We can be sure to expedite many of the steps if needed.

Overall, please let us know if this idea would be of interest to your group, and if it is, if you would like to discuss further with this smaller group before we reach out to the larger group to discuss the idea.

Thanks in advance for your consideration,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/6/2021 1:11:51 AM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmores]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Thomas Stock [b6] Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; David Douglas [b6]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika [b6]; Lawlor, Ciarán [b6]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris [b6]; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kueth, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Waring, Lorraine (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af91df8dec884f649cce10804470d1cb-Lorraine.Wa]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

Subject: ACTIV Cross Trial Operations Strategy/Problem Solving Meeting

Location: https://fnih.zoom.us/j/____b6____

Start: 9/17/2020 1:00:00 PM

End: 9/17/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every 2 week(s) on Thursday from 9:00 AM to 10:00 AM

Required Attendees: Higgs, Elizabeth (NIH/NIAID) [E]; Bugin, Kevin (FDA/CDER); Kim, Peter (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E];

Atkinson, Jane (NIH/NCATS) [E]; Patterson, Amy (NIH/NHLBI) [E]; Beigel, John (NIH) [E]; Dunsmore, Sarah (NIH/NCATS) [E]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Thomas Stock; Erhardt, William (HHS/IOS); Harrigan, Rachel (HHS/IOS); David Douglas; Douglas, David (HHS/IOS); Stock, Thomas (HHS/IOS)

Optional Attendees: Parker, CAPT Sheri (HHS/IOS); Philip, Ritika; Lawlor, Ciarán; Chen, Helen; Appell, Evan; Wholley, David (FNIH) [T];

Punturieri, Antonello (NIH/NHLBI) [E]; Boucher, Cynthia (NIH/NCATS) [E]; Teyhen, Deydre (HHS/IOS); Parker, Ashley (NIH/OD) [E]; VND Shreeve, Chris; Knox, Shamay (NIH/NIAID) [E]; Decastro, Philip (NIH/NIAID) [E]; Illanes, Christine (NIH/NIAID) [E]; Ramakrishnan, Raahul; Kuethe, Christine (OS/ASPR/BARDA) (CTR); Sorosa, Alex; Waring, Lorraine (OS/ASPR/BARDA); Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]

Dear NIH Trial Operational Representatives,

I am reaching out to you all because a need has been identified to get a small group of operationally focused problem solvers together across all the ACTIV and Convalescent Plasma trial that are being overseen by the NIH/ACTIV/OWS. The OWS liaison had been having a brief weekly meeting to discuss trial needs, but quickly realized that the discussions could benefit from having their NIH counterparts on the calls, as well.

The group as identified the following representative for each trial that would be in a position to not only understand the trial needs, but to help make operational decisions. If you feel we have identified you as the primary NIH representative to fill this role, please let us know.

ACTIV-1: Jane Atkinson (Cynthia Boucher, when Jane can't attend)

ACTIV-2: Peter Kim

ACTIV-3: Laura McNay

ACTIV-4/C3PO: Amy Patterson

ACTIV-5: John Beigel

NYU: Sarah Dunsmore

OWS: Lynn, Kevin, Sheri, Ciaran, Ritika, Tom, Bill, Rachel, Dave

ACTIV: Stacey, Helen, Evan

The purpose of these meetings will be to identify operational and logistical issues that could be causing issues for each of the trial and devise ways how OWS and ACTIV can best help to address them. We feel by having a joint meeting among the trials common issues could be solved by all in a similar manner and best practices could be shared to aid in issues that perhaps a single trial is facing.

Thank you so much for all you efforts and time. We know another meeting may be challenging to work it, but we hope it will be worth your time if we can help to solve challenges for each of your trials more quickly.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/6/2021 12:59:29 AM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmores]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Thomas Stock [b6]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; David Douglas [b6]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika [b6]; Lawlor, Ciarán [b6]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris [b6]; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kuethe, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Waring, Lorraine (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af91df8dec884f649cce10804470d1cb-Lorraine.Wa]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, Alan (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

Subject: Summary of the ACTIV Cross Trial Operations Strategy/Problem Solving Meeting 02/04/21
Attachments: ACTIV_Cross-Trial Ops Meeting_20210204.pdf; ACTIV_TX-Clinical_Biospecimen Priorization Committee
Overview_DRAFT_20210202 SR-sja-AS.pptx

Dear ACTIV Trial Ops Reps,

Thank you so much for a good meeting yesterday and sharing your thoughts on combining multiple routes of administration for the trials. Please find attached the summary and action items to the meeting. I have also pasted the action items below here as an extra reminder to send you ICFs if you have not (ACTIV-4b, ACTIV-4c, and C3PO) and to review the sample and ICF tables from the Biospecimen slides (also attached here).

Action Items

Information

Owner(s)

- | | |
|---|--------------------|
| 1. Around the biospecimen prioritization efforts – please have a team member take a look at the (2) slides comparing the language on the ICFs and looking at the sample collections and what might be there as a remaining sample – please give Stacey Adam feedback | ACTIV Teams |
| 2. Please get any ICFs to Stacey as soon as possible | ACTIV Teams |

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] | Mobile: [b6]
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/6/2020 1:12:36 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: [EXTERNAL] Introduction to NIH trial efforts

FYI. Just saw this, but indicative of a) conversations with companies on drugs moving forward but far from complete b) Keith Gottesdiener being really helpful here.

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 8:54 AM
To: Wholley, David (FNIH) [T] [b6]
Cc: elkim@deloitte.com
Subject: FW: [EXTERNAL] Introduction to NIH trial efforts

Hi David,

FYI, in case you need to know for your FC meeting this morning.

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Wednesday, May 6, 2020 8:54 AM
To: Rupert Vessey [b6]; Keith Gottesdiener [b6]; Jonathan Sadeh [b6]; Samit Hirawat [b6]
Cc: Keith (USE) Gottesdiener [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Eric Hughes [b6]
Subject: RE: [EXTERNAL] Introduction to NIH trial efforts

Thanks, Keith, I sincerely appreciate you making the connection for us to Rupert and his team.

Hi Rupert,

Thank you for your prompt response to Keith's message we are very excited to speak with you, Jonathan, and Samit about our hope to include abatacept in our upcoming master protocol, ACTT-3, that will be part of the ACTIV public-private partnership that was launched last month under Francis Collins direction. I am cc'ing my co-chairs, Sarah Read (NIH/NIAID) and Eric Hughes (Novartis), for our Clinical Therapeutics Working Group who is overseeing our efforts to prioritize compounds and design master protocols for them, so they are aware that we have connected. The three of us would like to chat with your team as soon as we are able to find a mutually agreeable time.

Please let me know who I should work with to organize schedules from your side and I will begin to get a meeting planned.

Thank you again for your interest and prompt response.

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Rupert Vessey <[b6]>

Sent: Wednesday, May 6, 2020 8:41 AM

To: Keith Gottesdiener [b6]; Jonathan Sadeh [b6]; Adam, Stacey (FNIH) [T] [b6]; Samit Hirawat <[b6]>

Cc: Keith (USE) Gottesdiener [b6]

Subject: Re: [EXTERNAL] Introduction to NIH trial efforts

Many thanks Keith

Stacey - good to make the connection. Jonathan has been running point on a lot of our clinical activity and of course Samit Hirawat is my close colleague and the CMO of BMS. We look forward to hearing more and are pleased to have the opportunity to participate in the NIH trial efforts.

Rupert

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From: Keith Gottesdiener [b6]

Sent: Wednesday, May 6, 2020 8:21:44 AM

To: Rupert Vessey [b6]; Jonathan Sadeh [b6]; Adam, Stacey (FNIH) [T] [b6]

Cc: Keith (USE) Gottesdiener [b6]

Subject: [EXTERNAL] Introduction to NIH trial efforts

Rupert and Jonathan:

I've updated you on the intersections of NIH and COVID R&D, and I'm happy to say one of BMS's compounds, apatacept was highly ranked in NIH prioritization efforts. While we have plans to study apatacept in the COVID R&D consortium trial (the PROMISE study), like COVID R&D and Takeda's decision to put the COVID R&D Hyper-IgG program into a different NIH trial, Stacey will be talking to you about a possibility to participate in a different trial called ACTT3. It may be that apatacept should find a different or possibly better home in the upcoming NIH trial Stacey can tell you about.

Stacey is a key member of the NIH Therapeutics Workstream for prioritization and clinical protocols development, and is a member of the NIH Foundation (FNIH).

If I can be of further help, let me know.

Best, Keith

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/5/2020 1:39:54 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: Biomarck -BIO-11006 ARDS compound for COVID 19

Thanks, David,

I will make sure it goes into our next round of review.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 9:31 AM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Lane, Cliff (NIH/NIAID) [E] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: Biomarck -BIO-11006 ARDS compound for COVID 19

Hi, Stacey

I had a half-hour productive conversation with Esther Krofah and Brenda Honeycutt from Faster Cures yesterday to update them on ACTIV and hear what they are doing in the COVID field. She cited 1) their tracker for COVID therapeutics and vaccines (which I thanked her for making available, as we have been using it in our Tx prioritization efforts) 2) some policy work they are doing with NIH, primarily NCATS, and their business council around the COVID response, which she says will be posted later this week on their website 3) a post-COVID "early warning" surveillance system for future pandemics they are looking to develop 4) an analysis of promising compounds that could be used in platform trials. The Biomarck drug below has apparently risen to the top of the heap as she put it. They had a meeting with BARDA last week that Esther claimed showed good safety and efficacy data out of a Phase II. I am simply sending this to you and to Ashley so it gets on our respective "lists" of things to consider if it is not already on there.

Thanks, David

From: Esther Krofah [b6]
Sent: Monday, May 4, 2020 12:13 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: Biomarck -BIO-11006 ARDS compound for COVID 19

Hi David,

It was great speaking with you and thanks for all you're doing. As mentioned, Biomarck Pharmaceuticals based in Research Triangle Park, N.C. has an asset BIO-11006 that has the potential first to market treatment option in ARDS. They have received Orphan Drug designation from the FDA and expect to obtain priority review in ARDS. Their Phase 2 data demonstrated a mortality reduction of >40% in ARDS patients. Announcement of their results is here: [click here](#). The compound has a well-established clinical safety profile with over 200 patients exposed and there is strong interest in accelerating into clinical trial for COVID-19. Please see the attached documents. They had a meeting with BARDA last week that went well and have submitted their Phase 2 data to FDA. Application number: IND070296. This would be a worthwhile company to speak with and consider for acceleration in the ACTIV therapeutic accelerator. I am happy to make an introduction or see contact information below to the Chairman of the company.

Rajin Ahuja | Executive Chairman of the Board
Biomarck Pharmaceuticals - 2530 Meridian Parkway Suite 300, Durham, NC 27713
C: [b6] | biomarck.com

All the best,
Esther



Esther Krofah
Executive Director
FasterCures
- | 202-336-8906 (office)

[b6]



From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/1/2020 6:28:13 PM
To: [REDACTED] b6
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: ACTIV partnership on COVID-19
Attachments: FNIH Covid 19 meeting April 03 2020 notes.docx

Dear Captain Burgess,

I am writing to you at the suggestion of Brigadier General Michael Talley. As you know well, addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. While the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond, the field needs to find a way to focus and prioritize these many efforts, as there is of course a critical need for effective treatments and vaccines.

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and of course working with other government agencies and individual companies on accelerated testing of vaccines and therapeutics. In order to broaden the response on April 17 we announced ACTIV, a new public-private partnership with FDA, BARDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics. We have since added representatives from the Veterans Administration and, in recognition of the valuable work and capabilities of the DoD in these and other fields of medical research, approached BG Talley earlier this week to see if there would be interest in adding representatives from the Department to our partnership.

As described in the attached meeting notes (from our kick-off on April 3) we have now set up Working Groups to decide efforts in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development. At the suggestion of BG Talley, I would like to invite you to join as a member on the Therapeutics - Clinical Working Group which is being co-chaired by Sarah Read, NIAID and Eric Hughes, Novartis. While this group has been meeting for several weeks, there are many decisions still to be made and many areas of discussion that can benefit from your insights and expertise.

Please direct your response to this invitation to Stacey Adam, [REDACTED] b6 of the Foundation for the NIH, who will fill you in on the mission and progress of the Working Group and get you integrated into meeting logistics. I look forward to your contributions to this critical effort.

Best,
Francis Collins

From: Prabha Fernandes [b6]
Sent: 5/1/2020 4:45:45 PM
To: 'Alvarez, Rosa Maria' [rosalvarez@deloitte.com]; [b6]
[b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; [b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas /US' [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: 'Young, John' [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: Data Request from Clinical Tx Prioritization Working Group
Attachments: In vitro promise of Aplidin for COVID-19 sends PharmaMar upwards.pdf

Dear Rosa-Maria,
In case you have missed this one from PharmaMar in Spain. Has started clinical testing.
Regards,
prabha

From: Alvarez, Rosa Maria <rosalvarez@deloitte.com>

Sent: Thursday, April 30, 2020 5:51 PM

To: [b6]
[b6] Baric, Ralph [b6]
[b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [b6]; Hewitt, Judith (NIH/NIAID) [E] [b6]; Deming, Damon (FDA/CDER) [b6]
[b6]; Parker, Ashley (NIH/OD) [E]
[b6] Adams, Peter (OS/ASPR/BARDA)
[b6]; Rao, Srinivas /US [b6] Qashu, Felicia (NIH/OD) [E]
Cc: Young, John [b6] Colvis, Christine (NIH/NCATS) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: Data Request from Clinical Tx Prioritization Working Group

Colleagues,

The ACTIV Clinical Therapeutics - Agent Prioritization Group put together a shortlist of clinical stage antivirals that could be go into the clinic – SEE BELOW. Because the amount of public information on the preclinical antiviral activity of these molecules is limiting, they've asked if any of the industry folks on our Preclinical Working Group have tested any of these molecules against SARS-CoV-2 and, if so, if they would be willing to share the corresponding EC50, EC90 and CC50 values

(and if there is any data using Remdesivir as a comparator). Since this list was generated before early data on Remdesivir went public, there is hesitation in taking a compound to clinical trials that may have shown to be inferior to Remdesivir as predicted by an in vitro assay.

Please let us know if you have any questions. Any data you would be willing to share with the Clinical Tx group will be appreciated.

Regards,
Rosa

Clinical Stage Compound Prioritization – First Wave

Nelfinavir	Antiviral	protease inhibitor
Truvada (emtricitabine and tenofovir)	Antiviral	both HIV-1 nucleoside analog reverse transcriptase inhibitors HIV protease
Atazanavir	Antiviral	Inosine monophosphate dehydrogenase inhibitor
Ribavirin	Antiviral	oral ribonucleoside analog
EIDD-2801	Antiviral	Pyruvate synthase inhibitor
Nitazoxanide	Antiviral	Viral RNA polymerase
Favilavir/Favipiravir/T-705/ Avigan	Antiviral	Glutamate decarboxylase 2 (GAD2; GAD65)
Ivermectin (Long Acting Injectable)	Antiviral	transmembrane protease serine 2 (TMPRSS2) inhibitor
Camostat mesilate (FOIPAN)	Antiviral	inhibits the fungal-mediated synthesis of ergosterol
Itraconazole	Antiviral	

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: b6
www.deloitte.com

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/1/2020 4:09:06 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Dod invitation note #2: Capt. Timothy Burgess for TX-Clinical WG
Attachments: FNIH Covid 19 meeting April 03 2020 notes.docx

Francis and Ashley:

Here is note to Captain Burgess [REDACTED] b6
Captain Timothy H. Burgess
Director, Infectious Diseases Clinical Research Program
USUHS

Dear Captain Burgess,

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Best,
Francis Collins

From: Prabha Fernandes [b6]
Sent: 5/1/2020 12:12:17 AM
To: 'Alvarez, Rosa Maria' [rosalvarez@deloitte.com]; [b6]
[b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.ema]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; [b6]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas /US' [b6] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: 'Young, John' [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: Data Request from Clinical Tx Prioritization Working Group

Hello Rosa-Maria,
Here is the info
"Hi Prabha,

b5

Does it answer your question(s)?

Sasha

APAR0000005556

From: Alvarez, Rosa Maria <rosalvarez@deloitte.com>

Sent: Thursday, April 30, 2020 5:51 PM

To: [REDACTED] b6 [REDACTED] Baric, Ralph [REDACTED] b6 [REDACTED] b6 [REDACTED]; Ottinger, Elizabeth (NIH/NCATS) [E] [REDACTED] b6 [REDACTED]; Hewitt, Judith (NIH/NIAID) [E] [REDACTED] b6 [REDACTED] Deming, Damon (FDA/CDER) [REDACTED] b6 [REDACTED] Parker, Ashley (NIH/OD) [E] [REDACTED] b6 [REDACTED] Adams, Peter (OS/ASPR/BARDA) [REDACTED] b6 [REDACTED] Rao, Srinivas /US [REDACTED] b6 [REDACTED] Qashu, Felicia (NIH/OD) [E] [REDACTED] b6 [REDACTED]
Cc: Young, John [REDACTED] b6 [REDACTED]; Colvis, Christine (NIH/NCATS) [E] [REDACTED] b6 [REDACTED]; Menetski, Joseph (FNIH) [T] [REDACTED] b6 [REDACTED]
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Rosa M. Álvarez

APAR0000005556

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/5/2021 12:39:56 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina

[b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr], Nasr, Hana
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: Summary of the ACTIV-2/3 Trial Oversight Committee Meeting

Attachments: 2021-02-03_Trial_Oversight_Committee_Meeting_Summary.pdf

Dear ACTIV-2/3 TOC Members,

Attached is the summary of our meeting yesterday. Please note the follow items needed from the group in relation to the vaccine project and the assistance in reaching out to Regeneron for the joint outpatient monoclonal antibody analysis.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct. [b6] Mobile: [b6]

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



From: Prabha Fernandes [b6]
Sent: 4/30/2020 10:38:03 PM
To: 'Kara Carter' [b6]; 'Alvarez, Rosa Maria' [rosalvarez@deloitte.com], [b6]
[b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; [b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas /US' [b6] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: 'Young, John' [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: Data Request from Clinical Tx Prioritization Working Group

Correct.. it is being run at UNC

From: Kara Carter [b6]
Sent: Thursday, April 30, 2020 6:30 PM
To: Prabha Fernandes [b6]; 'Alvarez, Rosa Maria' <rosalvarez@deloitte.com>; [b6]; [b6] 'Baric, Ralph' [b6] 'Ottinger, Elizabeth (NIH/NCATS) [E]' [b6] 'Hewitt, Judith (NIH/NIAID) [E]' [b6] 'Deming, Damon (FDA/CDER)' [b6] 'Parker, Ashley (NIH/OD) [E]' [b6] 'Adams, Peter (OS/ASPR/BARDA)' [b6] 'Rao, Srinivas /US' [b6] 'Qashu, Felicia (NIH/OD) [E]' [b6]
Cc: 'Young, John' [b6] 'Colvis, Christine (NIH/NCATS) [E]' [b6] 'Menetski, Joseph (FNIH) [T]' [b6]
Subject: RE: Data Request from Clinical Tx Prioritization Working Group

George and other published EIDD-2801 in the attached publication. It has been licensed to Ridgeback and they started Phase I already.



Kara Carter, PhD
Executive Vice President Infectious Disease

[b6]
www.evotec.com

APAR0000005598

From: Prabha Fernandes [b6]
Sent: Thursday, April 30, 2020 6:29 PM
To: Kara Carter [b6]; 'Alvarez, Rosa Maria' [b6]
[b6]
[b6] 'Baric, Ralph' [b6] 'Ottinger, Elizabeth (NIH/NCATS) [E]'
[b6] 'Hewitt, Judith (NIH/NIAID) [E]' [b6] 'Deming, Damon (FDA/CDER)'
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'Menetski, Joseph (FNIH) [T]' [b6]
Subject: RE: Data Request from Clinical Tx Prioritization Working Group

[EXTERNAL]

Hi Rosa and Kara,
OK.. then I will get the EIDD compound only..
Prabha

From: Kara Carter [b6]
Sent: Thursday, April 30, 2020 6:18 PM
To: Alvarez, Rosa Maria <rosalvarez@deloitte.com> [b6]
[b6] Baric, Ralph
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Cc: Young, John [b6] Colvis, Christine (NIH/NCATS) [E] [b6] Menetski, Joseph (FNIH) [T] [b6]
Subject: RE: Data Request from Clinical Tx Prioritization Working Group

Rosa,

All of these compounds except EIDD-2801 are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here <https://reframedb.org/assays/A00440>. You can create an account for free and search the data. I hope that helps.

Best,
Kara



Kara Carter, PhD
Executive Vice President Infectious Disease
[b6] (Mobile)

APAR0000005598

b6

www.evotec.com

From: Alvarez, Rosa Maria <rosalvarez@deloitte.com>

Sent: Thursday, April 30, 2020 5:51 PM

To: [REDACTED] b6; Kara Carter [REDACTED] b6; Baric, Ralph [REDACTED] b6

[REDACTED] b6; Ottinger, Elizabeth (NIH/NCATS [E] [REDACTED] b6; Hewitt, Judith (NIH/NIAID) [E] [REDACTED] b6; Deming, Damon (FDA/CDER) [REDACTED] b6

[REDACTED] b6; Parker, Ashley (NIH/OD) [E] [REDACTED] b6; Adams, Peter (OS/ASPR/BARDA)

[REDACTED] b6; Rao, Srinivas /US [REDACTED] b6; Qashu, Felicia (NIH/OD) [E]

Cc: Young, John [REDACTED] b6; Colvis, Christine (NIH/NCATS) [E] [REDACTED] b6; Menetski, Joseph (FNIH) [T] [REDACTED] b6

Subject: Data Request from Clinical Tx Prioritization Working Group

[EXTERNAL]

Colleagues,

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Regards,
Rosa

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Atazanavir	Antiviral	HIV protease
Ribavirin	Antiviral	Inosine monophosphate dehydrogenase inhibitor
EIDD-2801	Antiviral	oral ribonucleoside analog
Nitazoxanide	Antiviral	Pyruvate synthase inhibitor
Favilavir/Favipiravir/T-705/ Avigan	Antiviral	Viral RNA polymerase
Ivermectin (Long Acting Injectable)	Antiviral	Glutamate decarboxylase 2 (GAD2; GAD65)

APAR0000005598

Camostat mesilate (FOIPAN)	Antiviral	transmembrane protease serine 2 (TMPRSS2) inhibitor
Itraconazole	Antiviral	inhibits the fungal-mediated synthesis of ergosterol

Rosa M. Álvarez
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Mobile: b6
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From: Prabha Fernandes [b6]
Sent: 4/30/2020 10:34:25 PM
To: 'Alvarez, Rosa Maria' [rosalvarez@deloitte.com]; [b6]
[b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; [b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas /US' [b6] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: 'Young, John' [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: Data Request from Clinical Tx Prioritization Working Group

Hello Rosa,

EIDD has a totally different mode of action than Remdesivir and belongs to a different class (nucleoside). Comparing potencies in vitro between two different classes of drugs will be like comparing apples and oranges. Note we discussed PK and levels at the infections site. As long as that drug level is several fold the IC50 that is good. Let us not look at simple IC50s. For example, Remdesivir is a good start but does not clear virus. Favipiravir is far less potent in vitro but clears the virus in humans.

Regards,

Prabha

From: Alvarez, Rosa Maria <rosalvarez@deloitte.com>

Sent: Thursday, April 30, 2020 5:51 PM

To: [b6]
[b6] Baric, Ralph [b6]
[b6] Ottinger, Elizabeth (NIH/NCATS) [E] [b6] Hewitt, Judith (NIH/NIAID) [E] [b6] Deming, Damon (FDA/CDER) [b6]
[b6] Parker, Ashley (NIH/OD) [E]
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[b6] Rao, Srinivas /US [b6] Qashu, Felicia (NIH/OD) [E]
Cc: Young, John [b6] Colvis, Christine (NIH/NCATS) [E] [b6] Menetski, Joseph (FNIH) [T] [b6]
Subject: Data Request from Clinical Tx Prioritization Working Group

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Regards,
Rosa

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Camostat mesilate (FOIPAN)	Antiviral	inhibits the fungal-mediated synthesis of ergosterol
Itraconazole	Antiviral	

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: () b6
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From: Prabha Fernandes [b6]
Sent: 4/30/2020 10:28:35 PM
To: 'Kara Carter' [b6]; 'Alvarez, Rosa Maria' [rosalvarez@deloitte.com], [b6]
[b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
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Cc: Young, John [b6]; Colvis, Christine (NIH/NCATS) [E]; [b6]; Menetski, Joseph (FNIH) [T] [b6]
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Best,
Kara



Kara Carter, PhD
Executive Vice President Infectious Disease

b6 (Mobile)

b6
www.evotec.com

From: Alvarez, Rosa Maria <rosalvarez@deloitte.com>

Sent: Thursday, April 30, 2020 5:51 PM

To: b6; Kara Carter; b6; Baric, Ralph; b6; Ottinger, Elizabeth (NIH/NCATS [E]; b6; Hewitt, Judith (NIH/NIAD) [E]; b6; Deming, Damon (FDA/CDER); b6; Parker, Ashley (NIH/OD) [E]; b6; Adams, Peter (OS/ASPR/BARDA); b6; Rao, Srinivas /US; b6; Qashu, Felicia (NIH/OD) [E]; b6

Cc: Young, John; b6; Colvis, Christine (NIH/NCATS) [E]; b6; Menetski, Joseph (FNIH) [T]; b6

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[EXTERNAL]

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Rosa M. Álvarez
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From: Prabha Fernandes [b6]
Sent: 4/30/2020 10:27:44 PM
To: 'Alvarez, Rosa Maria' [rosalvarez@deloitte.com]; [b6]
[b6]
[b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; [b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas /US' [b6] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
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Subject: RE: Data Request from Clinical Tx Prioritization Working Group

Dear Rosa Maria,

Thank you.

One of my colleagues who is also a proposed expert reviewer is the inventor of EIDD-2801 and I can get you the data from him

Favipiravir is from Toyama (Fujifilm), a company I have worked with for more than 3 decades and still help and I can get the data for that

Ivermectin: I have a paper for review on Ivermectin and will check on what is available.

Regards,

Prabha

From: Alvarez, Rosa Maria <rosalvarez@deloitte.com>

Sent: Thursday, April 30, 2020 5:51 PM

To: [b6]
[b6]
[b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [b6] Hewitt, Judith (NIH/NIAID) [E] [b6] Deming, Damon (FDA/CDER) [b6]
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Truvada (emtricitabine and tenofovir)	Antiviral	both HIV-1 nucleoside analog reverse transcriptase inhibitors HIV protease
Atazanavir	Antiviral	Inosine monophosphate dehydrogenase inhibitor
Ribavirin	Antiviral	oral ribonucleoside analog
EIDD-2801	Antiviral	Pyruvate synthase inhibitor
Nitazoxanide	Antiviral	Viral RNA polymerase
Favilavir/Favipiravir/T-705/ Avigan	Antiviral	Glutamate decarboxylase 2 (GAD2; GAD65)
Ivermectin (Long Acting Injectable)	Antiviral	transmembrane protease serine 2 (TMPRSS2) inhibitor
Camostat mesilate (FOIPAN)	Antiviral	inhibits the fungal-mediated synthesis of ergosterol
Itraconazole	Antiviral	

Rosa M. Álvarez
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Please let us know if you have any questions. Any data you would be willing to share with the Clinical Tx group will be appreciated.

Regards,
Rosa

Clinical Stage Compound Prioritization – First Wave

Nelfinavir	Antiviral	protease inhibitor
Truvada (emtricitabine and tenofovir)	Antiviral	both HIV-1 nucleoside analog reverse transcriptase inhibitors HIV protease
Atazanavir	Antiviral	Inosine monophosphate dehydrogenase inhibitor
Ribavirin	Antiviral	oral ribonucleoside analog
EIDD-2801	Antiviral	Pyruvate synthase inhibitor
Nitazoxanide	Antiviral	Viral RNA polymerase
Favilavir/Favipiravir/T-705/ Avigan	Antiviral	Glutamate decarboxylase 2 (GAD2; GAD65)
Ivermectin (Long Acting Injectable)	Antiviral	transmembrane protease serine 2 (TMPRSS2) inhibitor
Camostat mesilate (FOIPAN)	Antiviral	inhibits the fungal-mediated synthesis of ergosterol
Itraconazole	Antiviral	

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/4/2021 1:42:23 AM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmores]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Thomas Stock [b6]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; David Douglas [b6]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika [b6]; Lawlor, Ciarán [b6]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris [b6]; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kuethe, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Waring, Lorraine (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af91df8dec884f649cce10804470d1cb-Lorraine.Wa]; Lerner, Andrea

(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, Alan (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

Subject: ACTIV Cross Trial Operations Strategy/Problem Solving Meeting

Attachments: ACTIV_CP_CrossTrial_Ops_20210204.pdf

Location: <https://fnih.zoom.us/j/92111111111> b6

Start: 2/4/2021 2:00:00 PM

End: 2/4/2021 3:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Thursday from 9:00 AM to 10:00 AM

Required Attendees: Higgs, Elizabeth (NIH/NIAID) [E]; Bugin, Kevin (FDA/CDER); Kim, Peter (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E];

Atkinson, Jane (NIH/NCATS) [E]; Patterson, Amy (NIH/NHLBI) [E]; Beigel, John (NIH) [E]; Dunsmore, Sarah (NIH/NCATS) [E]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Thomas Stock; Erhardt, William (HHS/IOS); Harrigan, Rachel (HHS/IOS); David Douglas; Douglas, David (HHS/IOS); Stock, Thomas (HHS/IOS)

Optional Attendees: Wholley, David (FNIH) [T]; Parker, CAPT Sheri (HHS/IOS); Philip, Ritika; Lawlor, Ciarán; Chen, Helen; Appell, Evan; Punturieri, Antonello (NIH/NHLBI) [E]; Boucher, Cynthia (NIH/NCATS) [E]; Teyhen, Deydre (HHS/IOS); Parker, Ashley (NIH/OD) [E]; VND Shreeve, Chris; Knox, Shamay (NIH/NIAID) [E]; Decastro, Philip (NIH/NIAID) [E]; Illanes, Christine (NIH/NIAID) [E]; Ramakrishnan, Raahul; Kuethe, Christine (OS/ASPR/BARDA) (CTR); Sorosa, Alex; Waring, Lorraine (OS/ASPR/BARDA); Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]

Dear NIH Trial Operational Representatives,

Please find attached the slides for tomorrow's meeting.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/25/2020 5:57:13 PM
To: Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #8 - Stats Only
Attachments: IND 147771 SN00eb 5.3.5.1 Protocol No. 20-0006 - v4.0, 19Apr2020.eCTD.docx

Hi All,

ACTT2 v4.0

Sorry for not distributing this sooner.

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T]

Sent: Thursday, April 23, 2020 9:37 PM

To: Adam, Stacey (FNIH) [T]; Collins, Sylva (FDA/CDER); Eric Hughes; Lisa LaVange; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Bozzette, Sam (NIH/NCATS) [E]; De Claro, R. Angelo (FDA/CDER)

APAR0000005688

Cc: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #8 - Stats Only

When: Saturday, April 25, 2020 1:30 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us> **b6**

Hi TX-Clinical Master Protocol Subgroup,

Reminder this will mainly be a meeting to discuss the sample size and recovery ratio.

Thanks,

Stacey

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Password: **b6**

Find your local number: <https://fnih.zoom.us> **b6**

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 1/17/2021 5:13:59 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [dana.carluccio@roseliassociates.com]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina

[b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: Canceled: ACTIV-2/3 Trial Oversight Committee Meeting

Location: <https://fnih.zoom.us> [b6]

Start: 1/20/2021 8:00:00 PM

End: 1/20/2021 9:00:00 PM

Show Time As: Free

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Neaton, Jim; Lundgren, Jens; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Dear ACTIV-2/3 TOC Members,

Per our email discussion, we will be canceling this meeting due to many of our federal colleagues being off for the federal holiday, and because we can likely keep things moving via email this week. Thank you all for your quick responses and your flexibility.

Thanks,
Stacey

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From: Jim Neaton [b6]
Sent: 1/16/2021 12:10:46 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaefe06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: Re: Summary of the ACTIV-2/3 Trial Oversight Committee Meeting

Hi Stacey - I am ok skipping next week.

Thanks.

Jim

On Fri, Jan 15, 2021 at 4:54 PM Adam, Stacey (FNIH) [T] {b6} wrote:

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In addition, I also wanted to check in with the group about the call next Wednesday. I know that for many of our Federal team members it is a holiday due to the inauguration and I have already received some declines to attend. ***Does the team wish to continue with the meeting or cancel and regroup the following week? Please let me know if you have a preference.***

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

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APAR0000005738



From: Read, Sarah (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=527B160038004A199AE6E0BAC2226099-READSA]
Sent: 1/16/2021 1:57:50 AM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [dana.carluccio@roseliassociates.com]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina

[b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr], Nasr, Hana
[b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]
Subject: Re: Summary of the ACTIV-2/3 Trial Oversight Committee Meeting

I'm fine either way. Thanks!

On Jan 15, 2021, at 8:29 PM, Currier, Judith, M.D. [b6] wrote:

I would be fine with skipping next week if others decide this is best. Hoping for calm.
Judy

From: "Adam, Stacey (FNIH) [T]" [b6] >
Date: Friday, January 15, 2021 at 2:54 PM
To: "Wholley, David (FNIH) [T]" [b6], "Woodcock, Janet (FDA/CDER)" [b6], "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" [b6], "Bozzette, Sam (NIH/NCATS) [E]" [b6], "Read, Sarah - DAIDS" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Erbelding, Emily (NIH/NIAID) [E]" [b6], "Eakin, Ann (NIH/NIAID) [E]" [b6], Erica Ollmann Saphire [b6], "Stein, Peter (FDA/CDER)" [b6], Judy Currier [b6], Davey Smith [b6], Peter Kim [b6], James Neaton [b6], "Lundgren, Jens" [b6], "Higgs, Elizabeth (NIH/NIAID) [E]" [b6], "Kiley, James (NIH/NHLBI) [E]" [b6], "Goff, David (NIH/NHLBI) [E]" [b6]
Cc: "Chen, Helen" <qingchen@deloitte.com>, "Bugin, Kevin (FDA/CDER)" [b6], "Carver, Trea (NIH) [C]" [b6], "Reich, Colleen" [b6], Lisbeth Jørgensen [b6], Rose Li Central Account <FNIH@roseliassociates.com>, Dana Carluccio [b6], "Church, Elizabeth (NIH/NIAID) [E]" [b6], "Teyhen, Deydre (HHS/IOS)" [b6], "Sorosa, Alex" <asorosa@deloitte.com>, "Erhardt, William (HHS/IOS)" [b6], "Melencio, Cheryl (FNIH) [T]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], Mina Jabarkhail [b6], "Harrigan, Rachel (HHS/IOS)" [b6], "Nasr, Hana" <hanasr@deloitte.com>
Subject: Summary of the ACTIV-2/3 Trial Oversight Committee Meeting

CAUTION - EXTERNAL EMAIL: Do not click links or open attachments unless you recognize the sender.

Dear ACTIV-2/3 TOC Members,

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Thanks,
Stacey

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Director, Cancer

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From: Erbeling, Emily (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E976EBF7B14142FBB3C5C294EFB334FE-ERBELDINGEJ]
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Director, Cancer
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 1/8/2021 11:56:02 PM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmores]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Thomas Stock Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; David Douglas [b6]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika [b6]; Lawlor, Ciarán [b6]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris [b6]; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kuethe, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Waring, Lorraine

(/OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=af91df8dec884f649cce10804470d1cb-Lorraine.Wa]

Subject: Summary of the ACTIV Cross Trial Operations Strategy/Problem Solving Meeting

Attachments: ACTIV_Cross-Trial Ops Meeting_20210107.pdf

Dear ACTIV Trial Ops Leads,

Please find attached the summary and action items from our meeting yesterday. If you have any additions or amendments, please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

Direct: [b6] Mobile: [b6]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/16/2020 12:18:07 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6] [b6] k; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]; Hayden, Frederick G (fgh) [b6]; Gregory Sempowski [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userbdbe3d08]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Tressler, Randall (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tresslerf]; Koup, Richard (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33f3958c4eb34e619306d6991297f922-rkoup]; Sullivan, Nancy (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86e5e2580a6a44c6a2611fd510de6c96-njsull]; David Montefiori, Ph.D. [b6]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]

Subject: Ad Hoc ACTIV-2/-3 Trial Oversight Committee Meeting with ASC Members

Location: <https://fnih.zoom.us> [b6]

Start: 12/16/2020 8:00:00 PM

End: 12/16/2020 9:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; Hayden, Frederick G (fgh); Gregory Sempowski; Marovich, Mary (NIH/NIAID) [E]; Tressler, Randall (NIH/NIAID) [E]; Koup, Richard (NIH/VRC) [E]; Sullivan, Nancy (NIH/VRC) [E]; David Montefiori, Ph.D.; Aggarwal, Neil (NIH/NHLBI) [E]

Dear ACTIV-2/-3 TOC Members,

As noted by the change in the title of the meeting, we will be changing this TOC meeting to an Ad Hoc TOC to allow for the attendance of the ASC members for the discussion of the independent testing data and their suggestions for its use.

This discussion will take place after our usual general trial updates.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/19/2020 9:21:00 PM
To: Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Grund, Birgit [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2d226c78964db2a63a416a6acc2bae-birgit.umh]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; David Douglas [b6]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hochman, Judith [b6]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; [b6]; Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; LaVange, Lisa M [b6]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; [b6]; [b6] Leifer, Eric (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82f6ef6b63654d1294890664f81c9c95-leifere]; WahedA@edc.pitt.edu; Scott Berry [b6]; Wright, Clinton (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e18bd48748f4d7dab41338948aa9a59-wrightclb]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; [b6]; [b6] Thomas Stock [b6]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc];
CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Dana Carluccio
[b6]; Rose Li Central Account [FNIH@roseliassociates.com], Philip, Ritika
[b6] Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Marks, Gilbert
(OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group
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[b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Teyhen, Deydre (HHS/IOS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Puntunieri, Antonello
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Nayak, Seema (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Ramakrishnan, Raahul
[b6]; Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Nasr, Hana [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: Summary of the ACTIV Cross Trial Meeting

Attachments: 2020-12-18_Cross-Trial_Meeting_Summary.pdf

Dear ACTIV Trial Leads, OWS reps, and ACTIV WG reps,

Please find attached the summary and action items from our meeting yesterday. Thank you all for a great conversation on the biospecimen use prioritization discussion. Per the action items, we will be working up a strawman for you feedback and consideration in the new year.

Until that point, please will each trial send me you current ICF if you have done so already.

If you have any questions or amendments to the summary, please contact me.

Thanks,
Stacey

Stacey J. Adam, PhD
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Direct: [b6] Mobile: [b6]

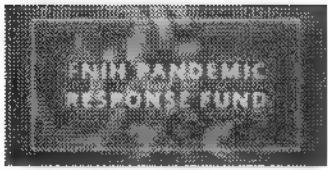
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Subject: Summary of the ACTIV Cross Trial Operations Strategy/Problem Solving Meeting

Attachments: ACTIV_Cross-Trial Ops Meeting_20201217.pdf

Dear ACTIV Trial Ops Teams,

Thank you all for a very productive year! It has been a pleasure working with you all!

Please find attached the summary of our meeting from yesterday, including action items and a link to the webinar that Janet gave to AARP. If you have any additions or amendments, please let me know.

I wish you all a safe and happy holiday season!

Warmest regards,
Stacey

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Subject: Follow up from the ACTIV Cross Trial Operations Strategy/Problem Solving Meeting 11/19/2020

Attachments. ACTIV_Cross-Trial Ops Meeting_20201119.pdf; CEAL Presentation to ACTIV_20201119.pptx; CEAL Communications Materials.zip

Dear ACTIV Cross Trial Ops participants,

Thank you so much for a great meeting last week. My apologies that it has taken us so long to follow up. Please find attached the summary and action items from the meeting. If you have any additions or amendments, please let me know.

In addition, I am sharing the materials from the CEAL team that Dr. Mensah discussed during his presentation. Please feel free to use this for your trials and modify them as needed. To access the information in the .zip file and at the link below please use the password: b6

- <https://covid19community.nih.gov>
- <https://www.nih.gov/news-events/community-engagement-alliance-against-covid-19-disparities-ceal-social-media-resources>

If you have any questions, please feel free to contact us.

Happy Thanksgiving to all,
Stacey

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CC: Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Lawlor, Ciarán [b6]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris [b6]; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kueth, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Waring, Lorraine

(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: Follow-up to the ACTIV Cross Trial Operations Strategy/Problem Solving Meeting 12/03/2020

Attachments: ACTIV_Cross-Trial Ops Meeting_20201203.pdf

Dear ACTIV Cross Trial Operations Team Members,

Please find attached the summary of our meeting last Thursday morning. If you have any additions or amendments, please let me know. Per the action items below, I am asking all the trials to please send me their ICFs, so we can review for ability to save and use sample for future research.

Please let these to myself and Helen Chen (qingchen@deloitte.com) as soon as you can.

Action Items		
	Information	Owner(s)
1.	Review trial-specific content on the HHS portal and let Chris Shreeve know if any changes are needed	ACTIV Trial Leads
2.	Check with HHS on the requirement / process for IRB review of the website content	Chris Shreeve
3.	Share ICF with Stacey Adam and denote the following: 1) whether the trial team would have leftover samples; 2) whether the trial team is willing to contribute to the central repository; 3) any issues and/or barriers	ACTIV Trial Leads
4.	Follow up with CONNECTS colleagues to understand the status of their central repository effort	Stacey Adam

In addition, please let me know if you have topics for future Cross Trial Operations meetings both the remainder of this year and in 2021. If you send them to me we will work to prioritize and queue up across the trials.

Thanks,
Stacey

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Dana Carluccio
[b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Parker, CAPT Sheri
(HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Marks, Gilbert
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(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: Summary of the ACTIV Cross Trial Meeting 01/29/21

Attachments: 2021-1-29_Cross-Trial_Meeting_Summary.pdf; ACTIV_Monthly Cross-Trial Meeting_20220129.pdf

Dear ACTIV Trial Leads,

Thank you so much for a great meeting yesterday. We really appreciate all of your engagement. Please find attached the summary of the meeting. Please let us know if you have any additions or amendments.

In addition, I am reattaching the slides. Again, if you have any further feedback on the Biospecimen Prioritization Committee and Process, please let us know before 5pm ET on Tuesday, February 2nd.

Kind regards,
Stacey

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[b6] Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr], Nasr, Hana
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: Slides and Summary of the ACTIV-2/3 Trial Oversight Committee Meeting

Attachments: 2021-01-06_Trial_Oversight_Committee_Meeting_Summary.pdf; ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210106v2.pdf

Dear ACTIV-2/3 TOC Members,

Please find attached both the slides from yesterday's meeting, as well as the summary. If you have any additions or amendments to the summary please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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Subject: Slides for ACTIV-2/-3 Trial Oversight Committee Meeting
Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201215.pdf

Hi Everyone,

Apologies for not getting these sent sooner, but please find attached the slides for today's meeting in case the zoom is troublesome.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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Subject: Materials for ACTIV Cross Trial Meeting 01/29/21

Attachments: ACTIV_Monthly Cross-Trial Meeting_20220129.pdf; mpRCT interim presentation_v21-slides 22 and 23 corrected.pdf;
Lilly SARS-CoV-2 Neutralizing Antibody Program Update[1].pdf

Dear ACTIV Trial Leads,

We look forward to our meeting tomorrow. Please find attached the materials for the meeting.

1. Meeting Slides – Please take special care to review the second section of the presentation ahead of the meeting. This is the strawman for the Biospecimen Prioritization Process that we discussed at our last meeting. We put this together and reviewed it with your operations leads and a few representatives from the trials to get some early feedback, so we hope you will feel this reflects the process that we discussed. We will be soliciting any feedback this group may have for refinements before it goes to ACTIV leadership for approval and then we begin operationalizing the process.
2. In addition, please find the link to the colchicine study (<https://medrx.v.org/content/short/2021.01.26.21250494v1>) below and attached the recently made public slides from the ACTIV-4a trial that will be and the BLAZE-1/2 trial results that were presented by Lilly on Wednesday. These studies in addition to the tocilizumab data in the meeting slides will serve as part of the context for the final discussion in the meeting. We will be talking about how recent trial readouts could be changing clinical treatment guidelines, but at the very least are likely to cause alterations to our trials. The ACTIV-1, ACTIV-2, and ACTIV-4a PIs have all kindly agreed to help us present these findings and lead the discussion on their implications to our trials.

As always, thank you all for your time and efforts on these trials and for making time to come and review important cross trial topics with this group.

Kind regards,
Stacey

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CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]
Subject: Summary of the ACTIV-2/-3 Trial Oversight Committee Meeting
Attachments: 2020-12-09_Trial_Oversight_Committee_Meeting_Summary.pdf

Dear ACTIV-2/3 TOC Members,

Please find attached the summary of the meeting. If you have any additions or amendments, please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 1/29/2021 2:42:50 AM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmores]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Thomas Stock [b6]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; David Douglas [b6]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika [b6]; Lawlor, Ciarán [b6]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris [b6]; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kuethe, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Waring, Lorraine (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af91df8dec884f649cce10804470d1cb-Lorraine.Wa]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, Alan (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

Subject: Summary and Slides from the ACTIV Cross Trial Operations Strategy/Problem Solving Meeting 01/28/21

Attachments: ACTIV_Cross-Trial Ops Meeting_20210128.pdf; ACTIV_CP_CrossTrial_Ops_20210128.pdf

Dear ACTIV Trial Operations Leads,

Please find attached the slides, summary, and action items for our meeting this morning. Please let us know if you have any additions or amendments. Thank you all for a very productive discussion.

Once again, THANK YOU, Sheri and Rachel, for you service with this effort! We will miss you!

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

Direct: [b6] Mobile: [b6]

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/19/2020 6:45:59 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ODYSSEY Phase 3 interim results in COVID19 pneumonia

Hi Francis,

This compound is not currently in assessment by the ACTIV agent prioritization group.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, August 19, 2020 1:47 PM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: FW: ODYSSEY Phase 3 interim results in COVID19 pneumonia

Is this compound being considered by the therapeutic prioritization group?
FC

From: Mihael H. Polymeropoulos [b6]
Sent: Wednesday, August 19, 2020 1:38 PM
To: Fauci, Anthony (NIH/NIAID) [E] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]; Woodcock, Janet (FDA/CDER) [b6]
Subject: ODYSSEY Phase 3 interim results in COVID19 pneumonia

Dear Dr Fauci

Attached please find interim results from the Phase III study (60 of 300 patients) in severe COVID19 pneumonia, which we reported yesterday. We are very encouraged by these results which albeit preliminary show a [b4]

[b4] in favor of tradipitant in time to improvement at 7 days as compared to placebo. As you would recognize this magnitude of effect size, if confirmed, will be the largest of any therapeutics reporting such an endpoint that we are aware of.

We would like to understand whether you would be interested in collaborating to accelerate recruitment for this late stage asset. Tradipitant is in P3 for other indications and we already have scaled up to commercial grade supplies. Dr Woodcock is aware of the compound and its development in collaboration with the FDA. I will be available to discuss further at any time

Best regards

Mihael H. Polymeropoulos MD
CEO, Vanda Pharmaceuticals

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APAR0000008362

From: NIH Executive Secretariat [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7AF5A3E94AF34FD592E0FE4AB24C4BAD-ODEXECSEC1]
Sent: 6/18/2020 12:46:30 PM
To: [REDACTED] b6
Subject: Re: Cavid - Detecting and Monitoring Covid-19 Antibodies

Dear Ms. Morello –

Thank you for writing to the National Institutes of Health regarding the COVID-19 pandemic. We appreciate your interest in the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) collaboration, Rapid Acceleration of Diagnostics (RADx) initiative, or other NIH programs. Please submit your idea, candidate, or technology for consideration through the [NIH COVID 19 Portal](#).

With our sincere appreciation for your commitment to fighting the COVID-19 pandemic,

NIH Executive Secretariat
www.nih.gov



National Institutes of Health
Office of the Director/ Executive Secretariat

From: Charlotte Morello [REDACTED] b6
Sent: Wednesday, June 17, 2020 12:39 PM
To: Freire, Maria (FNIH) [T] [REDACTED] b6
Subject: Cavid - Detecting and Monitoring Covid-19 Antibodies

Hello Maria,

Cavid is the gold standard in HIV viral load monitoring around the world.

Since the onset of COVID-19, bioengineers at Cavid pivoted to adapt their technology to identify the presence of COVID-19 antibodies as well as the quantity and type of antibodies present. This is critical in determining whether or not a subject may have developed an immunity to the virus.

We are pleased to announce that Cavid will have their **ZIVA™ Analyzer ready to deploy in Q3 2020 to help fight against COVID-19**. The company is in discussions with governments, hospital systems, and private testing facilities regarding distribution of their easy-to-use benchtop system.

Would you like to speak with Cavid's Chairman, John Reisky de Dubnic to see how you can get involved with the fight against Covid-19?

Warm Regards,

Charlotte

Charlotte Morello
Managing Director
Force Weath
[REDACTED] b6
135 West 41st Street
New York, NY 10036

APAR0000008801

FORCE WEALTH

To: [\[redacted\]](#), please reply to this email

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 6/17/2020 5:22:28 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]
Subject: FW: Cavid - Detecting and Monitoring Covid-19 Antibodies

Hi Shannon and Rachel,

Can we please share as FYI to NIBIB/RADx and Dr. Schwetz? Also, I think we could share our standard response to direct them to the COVID-19 candidate and technologies portal – OK for ES to handle?

Thank you,
Ashley

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, June 17, 2020 1:13 PM
To: Menetski, Joseph (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E]
Subject: Re: Cavid - Detecting and Monitoring Covid-19 Antibodies

Ashley - please see below. M.

From: "Menetski, Joseph (FNIH) [T]" [b6]
Date: Wednesday, June 17, 2020 at 1:08:46 PM
To: "Freire, Maria (FNIH) [T]" [b6]
Subject: RE: Cavid - Detecting and Monitoring Covid-19 Antibodies

Interesting, thank you.

I will distribute as appropriate.

Joe

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, June 17, 2020 1:03 PM
To: Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: Cavid - Detecting and Monitoring Covid-19 Antibodies

From: Charlotte Morello [b6]
Sent: Wednesday, June 17, 2020 12:39 PM
To: Freire, Maria (FNIH) [T] [b6]
Subject: Cavid - Detecting and Monitoring Covid-19 Antibodies

Hello Maria,

Cavidi is the gold standard in HIV viral load monitoring around the world.

Since the onset of COVID-19, bioengineers at Cavidi pivoted to adapt their technology to identify the presence of COVID-19 antibodies as well as the quantity and type of antibodies present. This is critical in determining whether or not a subject may have developed an immunity to the virus.

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Warm Regards,

Charlotte

Charlotte Morello
Managing Director
Force Weather
b6
135 West 41st Street
New York, NY 10036

To [REDACTED], please reply to this email

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/2/2020 12:31:52 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dr Susanna Naggie, M.D. [b6]; Lundgren, Jens [b6]; Neaton, Jim [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; McNay, Laura (NIH/NIAID) [E] [b6]; Grund, Birgit [b6]; Judy Currier [b6]; David Douglas [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Michael Hughes [b6]; Kindzelski, Andrei (NIH/NHLBI) [E] [b6]; Hochman, Judith [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; LaVange, Lisa M [b6]; Beigel, John (NIH) [E] [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Erhardt, William (HHS/IOS) [b6]; Leifer, Eric (NIH/NHLBI) [E] [b6]; Scott Berry [b6]; Wright, Clinton (NIH/NINDS) [E] [b6]; Douglas, David (HHS/IOS) [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Bugin, Kevin (FDA/CDER) [b6]; Thomas Stock [b6]; Stock, Thomas (HHS/IOS) [b6]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Adrian Hernandez, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Springer, Jessica (NIH/NCATS) [E] [b6]; Lindsell, Chris [b6]; David Boulware [b6]; Collins, Sean P [b6]; Shotwell, Matthew Stephen [b6]; Brown, Samuel [b6]; Thompson, Taylor [b6]; Chen, Helen [qingchen@deloitte.com], Boucher, Cynthia (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Eric Hughes [b6]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Parker, CAPT Sheri (HHS/IOS) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Lawlor, Ciarán [b6]; Wholley, David (FNIH) [T] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [b6]; Groesch, Mary (NIH/NHLBI) [E] [b6]; Shipp, Allan (NIH/NHLBI) [E] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Nayak, Seema (NIH/NIAID) [E] [b6]; Lerner, Andrea (NIH/NIAID) [E] [b6]; Embry, Alan (NIH/NIAID) [E] [b6]; Birgit Grund [b6]; Ramakrishnan, Raahul [b6]; [b6]

CC:

Subject: ACTIV Cross Trial Meeting

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: <https://fnih.zoom.us> [b6]

Start: 8/28/2020 12:30:00 PM

End: 8/28/2020 2:00:00 PM

Show Time As: Busy

Recurrence: Monthly
the last Friday of every 1 month(s) from 8:30 AM to 10:00 AM

Required Attendees: Adam, Stacey (FNIH) [T]; Dr Susanna Naggie, M.D.; Jens Lundgren; Jim Neaton; Higgs, Elizabeth (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E]; Birgit Grund; Judy Currier; David Douglas; Smith, David; Kim, Peter (NIH/NIAID) [E]; Javan, Arzhang (NIH/NIAID) [E]; Michael Hughes; Kindzelski, Andrei (NIH/NHLBI) [E]; Hochman, Judith; Bozzette, Sam (NIH/NCATS) [E]; [b6]; Proschan, Michael (NIH/NIAID) [E]; LaVange, Lisa M; Beigel, John (NIH) [E]; Harrigan, Rachel (HHS/IOS); Erhardt, William (HHS/IOS) [b6]; [b6]

[b6]; Scott Berry; [b6]; Douglas, David (HHS/IOS);
Patterson, Amy (NIH/NHLBI) [E]; Bugin, Kevin (FDA/CDER); [b6] Thomas Stock;
Stock, Thomas (HHS/IOS); Erhardt, Bill (NIH/NIAID) [C]; Adrian Hernandez, M.D.; Dunsmore, Sarah (NIH/NCATS) [E];
Springer, Jessica (NIH/NCATS) [E]; Lindsell, Chris; David Boulware, Collins, Sean P; Shotwell, Matthew Stephen;
Samuel Brown; Taylor Thompson

Optional Attendees: qingchen@deloitte.com; Boucher, Cynthia (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Dana
Carluccio; Rose Li Central Account; Parker, CAPT Sheri (HHS/IOS); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Lawlor,
Ciarán; Wholley, David (FNIH) [T]; Teyhen, Deydre (HHS/IOS); Puntuneri, Antonello (NIH/NHLBI) [E]; Groesch, Mary
(NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Parker, Ashley (NIH/OD) [E]; Nayak, Seema (NIH/NIAID) [E];
Ramakrishnan, Raahul; Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Birgit Grund

Dear ACTIV-1/2/3/4/5/6 Trial Leads,

I just realized that our recurrence for this meeting would conclude this month, but we would like to
continue meeting so I am extending the invitation through the end of the year. We can re-evaluate if
that is the right end point once we are further into 2021.

Thanks,
Stacey

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To: Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Grund, Birgit [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2d226c78964db2a63a416a6acc2bae-birgit.um].; Judy Currier [b6] Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Leifer, Eric (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82f6ef6b63654d1294890664f81c9c95-leifere]; Wright, Clinton (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e18bd48748f4d7dab41338948aa9a59-wrightclb]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Nealm2@upmc.edu; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]; Leifer, Eric (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82f6ef6b63654d1294890664f81c9c95-leifere]; Wright, Clinton (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e18bd48748f4d7dab41338948aa9a59-wrightclb]; Scott Berry [b6]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; [b6] Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 [b6] Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia];
 [b6] Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [b6] Proschan, Michael
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Chen, Helen
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes
 [b6]; Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Marks, Gilbert
 (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Wholley, David (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfc346afd7671ee69f-Deydre.Teyh]; Punturieri, Antonello
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Groesch, Mary
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Embry, Alan (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Lerner, Andrea (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Read, Sarah (NIH/NIAID)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Philip, Ritika [Philip.Ritika@bcg.com]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Geller, Nancy L (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7470c942d4b6fa377d8695525e3ca-gellern]; Lawlor, Ciarán [b6]; Ramakrishnan, Raahul [b6]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Dr Susanna Naggie, M.D. [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]

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Start: 11/20/2020 1:30:00 PM

End: 11/20/2020 3:00:00 PM

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Recurrence: (none)

Required Attendees: [b6], David (HHS/IOS); Smith, David; Michael Hughes [b6]; [b6] Scott Berry; McNay, Laura (NIH/NIAID) [E]; [b6] Javan, Arzhang (NIH/NIAID) [E]; [b6] Kindzelski, Andrei (NIH/NHLBI) [E]; [b6] Bozzette, Sam (NIH/NCATS) [E]; Jim Neaton; Judy Currier; Higgs, Elizabeth (NIH/NIAID) [E]; LaVange, Lisa M; [b6] Proschan, Michael (NIH/NIAID) [E]; [b6] Patterson, Amy (NIH/NHLBI) [E]; Kim, Peter (NIH/NIAID) [E]; Birgit Grund; Hochman, Judith, Stock, Thomas (HHS/IOS); Thomas Stock; Erhardt, William (HHS/IOS); David Douglas; [b6] Bugin, Kevin (FDA/CDER); Beigel, John (NIH) [E]; Harrigan, Rachel (HHS/IOS); Jens Lundgren

Optional Attendees: Read, Sarah (NIH/NIAID) [E]; Dana Carluccio; Rose Li Central Account; Elsaid, Olivia; Nayak, Seema (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Philip, Ritika; Shipp, Allan (NIH/NHLBI) [E]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Geller, Nancy L (NIH/NHLBI) [E]; Lawlor, Ciarán; Ramakrishnan, Raahul; Teyhen,

Deydre (HHS/IOS); Groesch, Mary (NIH/NHLBI) [E]; Boucher, Cynthia (NIH/NCATS) [E]; Dr Susanna Naggie, M.D.; Wholley, David (FNIH) [T], Parker, CAPT Sheri (HHS/IOS); Embry, Alan (NIH/NIAID) [E], Punturieri, Antonello (NIH/NHLBI) [E]; Sorosa, Alex; Eric Hughes; qingchen@deloitte.com

Dear ACTIV-1/2/3/4/5 Trial Leads,

Moving a week earlier due to Thanksgiving.

Thanks,
Stacey

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To: Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Leifer, Eric (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82f6ef6b63654d1294890664f81c9c95-leifere]; Wright, Clinton (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e18bd48748f4d7dab41338948aa9a59-wrightcib]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Grund, Birgit [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2d226c78964db2a63a416a6acc2bae-birgit.umn.]; Judy Currier [b6]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]; Kindzelski, Andre (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; [b6]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; [b6] Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; [b6] Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Thomas Stock [b6]; Grund, Birgit [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2d226c78964db2a63a416a6acc2bae-birgit.umn.]; Hochman, Judith [b6] Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Wnght, Clinton (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6e18bd48748f4d7dab41338948aa9a59-wrightcib]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; [REDACTED] b6 [REDACTED]
[REDACTED] b6 [REDACTED]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; LaVange, Lisa M [REDACTED] b6 [REDACTED]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; David Douglas [REDACTED] b6 [REDACTED]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; [REDACTED] b6 [REDACTED] Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Leifer, Eric (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=82f6ef6b63654d1294890664f81c9c95-leifere]; Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]; [REDACTED] b6 [REDACTED]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Scott Berry [REDACTED] b6 [REDACTED]; WahedA@edc.pitt.edu
CC: Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [REDACTED] b6 [REDACTED] Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Lerner, Andrea (NIH/NIAID)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Dana Carluccio [b6]; Philip, Ritika [b6]; Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Dr Susanna Naggie, M.D. [b6]; Lawlor, Ciarán [b6]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Rose Li Central Account [FNIH@roseliassociates.com]; Ramakrishnan, Raahul [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]

Location: [https://fnih.zoom.us/j/\[b6\]](https://fnih.zoom.us/j/[b6])

Start: 12/18/2020 1:30:00 PM

End: 12/18/2020 3:00:00 PM

Show Time As: Busy

Recurrence: (none)

Required Attendees: [b6] McNay, Laura (NIH/NIAID) [E]; Jim Neaton; Harrigan, Rachel (HHS/IOS); [b6] Douglas, David (HHS/IOS); [b6] Patterson, Amy (NIH/NHLBI) [E]; Thomas Stock; Birgit Grund; Hochman, Judith; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6] Javan, Arzhang (NIH/NIAID) [E]; [b6]; Erhardt, William (HHS/IOS); LaVange, Lisa M; [b6] Jens Lundgren; Stock, Thomas (HHS/IOS); David Douglas; Proschan, Michael (NIH/NIAID) [E]; [b6] Beigel, John (NIH) [E]; Bozzette, Sam (NIH/NCATS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Bugin, Kevin (FDA/CDER), Lane, Cliff (NIH/NIAID) [E]; [b6] Michael Hughes; [b6] Kindzelski, Andrei (NIH/NHLBI) [E]; Judy Currier; Scott Berry; [b6]

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Grund, Birgit [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2d226c78964db2a63a416a6acc2bae-birgit.um].; Judy Currier [b6]; David Douglas [b6]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hochman, Judith [b6]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; [b6] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; LaVange, Lisa M [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; [b6]; [b6]; [b6]; Scott Berry [b6]; Wright, Clinton (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e18bd48748f4d7dab41338948aa9a59-wrightclb]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; [b6]; [b6] Thomas Stock [b6] Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Leifer, Eric (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82f6ef6b63654d1294890664f81c9c95-leifere]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]

CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Elsaid, Olivia [oelsaid@deloitte.com]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [b6]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Philip, Ritika [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Lawlor, Ciarán

[b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd], Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfc346afd7671ee69f-Deydre.Teyh]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Ramakrishnan, Raahul [b6]; Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]

Start: 10/30/2020 12:30:00 PM
End: 10/30/2020 2:00:00 PM

Recurrence: (none)

Required Attendees: Adam, Stacey (FNIH) [T]; Jens Lundgren; Jim Neaton; Higgs, Elizabeth (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E]; Birgit Grund; Judy Currier; David Douglas; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Javan, Arzhang (NIH/NIAID) [E]; Michael Hughes; Kindzelski, Andrei (NIH/NHLBI) [E]; Hochman, Judith; Bozette, Sam (NIH/NCATS) [E]; [b6]; Proshan, Michael (NIH/NIAID) [E]; LaVange, Lisa M; Beigel, John (NIH) [E]; Harrigan, Rachel (HHS/IOS); Erhardt, William (HHS/IOS); [b6]; [b6]; Leifer, Eric (NIH/NHLBI) [E]; [b6]; Scott Berry; [b6]; Wright, Clinton (NIH/NINDS) [E]; Douglas, David (HHS/IOS); Patterson, Amy (NIH/NHLBI) [E]; Bugin, Kevin (FDA/CDER); [b6]; Thomas Stock; Stock, Thomas (HHS/IOS)

Optional Attendees: qingchen@deloitte.com; Elsaid, Olivia; Boucher, Cynthia (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Dana Carluccio; Rose Li Central Account, Philip, Ritika; Parker, CAPT Sheri (HHS/IOS); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Lawlor, Ciarán; Wholley, David (FNIH) [T]; Teyhen, Deydre (HHS/IOS); Punturieri, Antonello (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Parker, Ashley (NIH/OD) [E]; Nayak, Seema (NIH/NIAID) [E]; Ramakrishnan, Raahul

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Grund, Birgit [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2d226c78964db2a63a416a6acc2bae-birgit.umn.]; Judy Currier [b6]; David Douglas [b6]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hochman, Judith [b6]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbb3e4-proscham]; LaVange, Lisa M [b6]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; stevewis@pitt.edu; [b6] Leifer, Eric (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82f6ef6b63654d1294890664f81c9c95-leifere]; [b6] Scott Berry [b6]; Wright, Clinton (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e18bd48748f4d7dab41338948aa9a59-wrightclb]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; [b6]; [b6] Thomas Stock [b6]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [b6]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group

CC:

(FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Lawlor, Ciarán
[b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Teyhen, Deydre (HHS/IOS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Punturieri, Antonello
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Groesch, Mary
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Nayak, Seema (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Ramakrishnan, Raahul
[b6]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, Alan
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Sorosa, Alex
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]

Start: 1/29/2021 1:30:00 PM
End: 1/29/2021 3:00:00 PM

Recurrence: (none)

Required Attendees: Adam, Stacey (FNIH) [T]; Jens Lundgren; Jim Neaton; Higgs, Elizabeth (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E];
Birgit Grund; Judy Currier; David Douglas; Smith, David; Kim, Peter (NIH/NIAID) [E]; Javan, Arzhang (NIH/NIAID) [E];
Michael Hughes; Kindzelski, Andrei (NIH/NHLBI) [E]; Hochman, Judith; Bozzette, Sam (NIH/NCATS) [E];
[b6]; Proshan, Michael (NIH/NIAID) [E]; LaVange, Lisa M; Beigel, John (NIH) [E]; Harrigan, Rachel
(HHS/IOS), Erhardt, William (HHS/IOS), [b6]
[b6] Scott Berry;
[b6] Douglas, David (HHS/IOS); Patterson, Amy (NIH/NHLBI) [E];
Bugin, Kevin (FDA/CDER), [b6] Thomas Stock; Stock, Thomas (HHS/IOS)
Optional Attendees: qingchen@deloitte.com; Boucher, Cynthia (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Dana
Carluccio; Rose Li Central Account; Parker, CAPT Sheri (HHS/IOS); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Lawlor,
Ciarán; Wholley, David (FNIH) [T]; Teyhen, Deydre (HHS/IOS); Punturieri, Antonello (NIH/NHLBI) [E]; Groesch, Mary
(NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Parker, Ashley (NIH/OD) [E]; Nayak, Seema (NIH/NIAID) [E];
Ramakrishnan, Raahul, Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Sorosa, Alex David

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 [b6]; Whooley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Teyhen, Deydre (HHS/IOS)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Punturieri, Antonello
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Groesch, Mary
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Parker, Ashley (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Nayak, Seema (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Ramakrishnan, Raahul
 [b6]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, Alan
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Dr Susanna Naggie, M.D.
 [b6]; Adrian Hernandez, M.D. [b6]

Start: 2/26/2021 1:30:00 PM
End: 2/26/2021 3:00:00 PM

Recurrence: (none)

Required Attendees: Adam, Stacey (FNIH) [T]; Jens Lundgren; Jim Neaton; Higgs, Elizabeth (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E];
 Birgit Grund; Judy Currier; David Douglas; Smith, David; Kim, Peter (NIH/NIAID) [E]; Javan, Arzhang (NIH/NIAID) [E];
 Michael Hughes; Kindzelski, Andrei (NIH/NHLBI) [E]; Hochman, Judith; Bozzette, Sam (NIH/NCATS) [E];
 [b6]; Proschan, Michael (NIH/NIAID) [E]; LaVange, Lisa M; Beigel, John (NIH) [E]; Harrigan, Rachel
 (HHS/IOS); Erhardt, William (HHS/IOS); [b6];
 [b6]; Scott Berry;
 [b6]; Douglas, David (HHS/IOS); Patterson, Amy (NIH/NHLBI) [E];
 Bugin, Kevin (FDA/CDER); [b6]; Thomas Stock; Stock, Thomas (HHS/IOS)
Optional Attendees: qingchen@deloitte.com; Boucher, Cynthia (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Dana
 Carluccio; Rose Li Central Account; Parker, CAPT Sheri (HHS/IOS); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Lawlor,
 Ciarán; Whooley, David (FNIH) [T]; Teyhen, Deydre (HHS/IOS); Punturieri, Antonello (NIH/NHLBI) [E]; Groesch, Mary
 (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Parker, Ashley (NIH/OD) [E]; Nayak, Seema (NIH/NIAID) [E];
 Ramakrishnan, Raahul; Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Dr Susanna Naggie, M.D.;
 Adrian Hernandez, M.D.

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dr Susanna Naggie, M.D. [b6]; Lundgren, Jens [b6]; Neaton, Jim [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; McNay, Laura (NIH/NIAID) [E] [b6]; Grund, Birgit [b6]; Judy Carrier [b6]; David Douglas [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Michael Hughes [b6]; Kindzelski, Andrei (NIH/NHLBI) [E] [b6]; Hochman, Judith [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; LaVange, Lisa M [b6]; Beigel, John (NIH) [E] [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Erhardt, William (HHS/IOS) [b6]; Leifer, Eric (NIH/NHLBI) [E] [b6]; Scott Berry [b6]; Wright, Clinton (NIH/NINDS) [E] [b6]; Douglas, David (HHS/IOS) [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Bugin, Kevin (FDA/CDER) [b6]; Thomas Stock [b6]; Stock, Thomas (HHS/IOS) [b6]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Adrian Hernandez, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Springer, Jessica (NIH/NCATS) [E] [b6]; Lindsell, Chris [b6]; David Boulware [b6]; Collins, Sean P [b6]; Shotwell, Matthew Stephen [b6]; Brown, Samuel [b6]; Thompson, Taylor [b6]

CC: Chen, Helen [qingchen@deloitte.com]; Boucher, Cynthia (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Eric Hughes [b6]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Parker, CAPT Sheri (HHS/IOS) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Lawlor, Ciarán [b6]; Wholley, David (FNIH) [T] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [b6]; Groesch, Mary (NIH/NHLBI) [E] [b6]; Shipp, Allan (NIH/NHLBI) [E] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Nayak, Seema (NIH/NIAID) [E] [b6]; Ramakrishnan, Raahul [b6]; Lerner, Andrea (NIH/NIAID) [E] [b6]; Embry, Alan (NIH/NIAID) [E] [b6]; Birgit Grund [b6]

Start: 5/21/2021 12:30:00 PM
End: 5/21/2021 2:00:00 PM
Show Time As: Busy

Recurrence: (none)

Required Attendees: Dr Susanna Naggie, M.D., Jens Lundgren; Jim Neaton, Higgs, Elizabeth (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E]; Birgit Grund, Judy Carrier, David Douglas; Smith, David; Kim, Peter (NIH/NIAID) [E]; Javan, Arzhang (NIH/NIAID) [E]; Michael Hughes; Kindzelski, Andrei (NIH/NHLBI) [E]; Hochman, Judith, Bozzette, Sam (NIH/NCATS) [E]; [b6]; Proschan, Michael (NIH/NIAID) [E]; LaVange, Lisa M; Beigel, John (NIH) [E]; Harrigan, Rachel (HHS/IOS); Erhardt, William (HHS/IOS); [b6]; Scott Berry; [b6]; Douglas, David (HHS/IOS); Patterson, Amy (NIH/NHLBI) [E]; Bugin, Kevin (FDA/CDER); [b6]; Thomas Stock; Stock, Thomas (HHS/IOS); Erhardt, Bill (NIH/NIAID) [C]; Adrian Hernandez, M.D.; Dunsmore, Sarah (NIH/NCATS) [E]; Springer, Jessica (NIH/NCATS) [E]; Lindsell, Chris; David Boulware, Collins, Sean P; Shotwell, Matthew Stephen; Samuel Brown; Taylor Thompson

Optional Attendees: [b6]hen@deloitte.com; Boucher, Cynthia (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Dana Carluccio; Rose Li Central Account; Parker, CAPT Sheri (HHS/IOS); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Lawlor, Ciarán; Wholley, David (FNIH) [T]; Teyhen, Deydre (HHS/IOS); Punturieri, Antonello (NIH/NHLBI) [E]; Groesch, Mary

(NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Parker, Ashley (NIH/OD) [E]; Nayak, Seema (NIH/NIAID) [E];
Ramakrishnan, Raahul; Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]

Dear ACTIV-1/2/3/4/5/6 Trial Leads,

Adjusting the May Cross ACTIV Meeting to accommodate the May ACTIV Executive Leadership Meeting.

Thanks,
Stacey

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dr Susanna Naggie, M.D. [b6]; Lundgren, Jens [b6]; Neaton, Jim [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; McNay, Laura (NIH/NIAID) [E] [b6]; Grund, Birgit [b6]; Judy Currier [b6]; David Douglas [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Michael Hughes [b6]; Kindzelski, Andrei (NIH/NHLBI) [E] [b6]; Hochman, Judith [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; LaVange, Lisa M [b6]; Beigel, John (NIH) [E] [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Erhardt, William (HHS/IOS) [b6]; Leifer, Eric (NIH/NHLBI) [E] [b6]; Scott Berry [b6]; Wright, Clinton (NIH/NINDS) [E] [b6]; Douglas, David (HHS/IOS) [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Bugin, Kevin (FDA/CDER) [b6]; Thomas Stock [b6]; Stock, Thomas (HHS/IOS) [b6]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Adrian Hernandez, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Springer, Jessica (NIH/NCATS) [E] [b6]; Lindsell, Chris [b6]; David Boulware [b6]; Collins, Sean P [b6]; Shotwell, Matthew Stephen [b6]; Brown, Samuel [b6]; Thompson, Taylor [b6]; Wholley, David (FNIH) [T] [b6]; Chen, Helen [qingchen@deloitte.com]; Boucher, Cynthia (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NCATS) [E] [b6]; Eric Hughes [b6]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Parker, CAPT Sheri (HHS/IOS) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Lawlor, Ciarán [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [b6]; Groesch, Mary (NIH/NHLBI) [E] [b6]; Shipp, Allan (NIH/NHLBI) [E] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Nayak, Seema (NIH/NIAID) [E] [b6]; Ramakrishnan, Raahul [b6]; Lerner, Andrea (NIH/NIAID) [E] [b6]; Embry, Alan (NIH/NIAID) [E] [b6]; Birgit Grund [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

CC:

Start: 4/30/2021 12:30:00 PM
End: 4/30/2021 2:00:00 PM

Recurrence: (none)

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dr Susanna Naggie, M.D. [b6]; Lundgren, Jens [b6]; Neaton, Jim [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; McNay, Laura (NIH/NIAID) [E] [b6]; Grund, Birgit [b6]; Judy Currier [b6]; David Douglas [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Michael Hughes [b6]; Kindzelski, Andrei (NIH/NHLBI) [E] [b6]; Hochman, Judith [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; LaVange, Lisa M [b6]; Beigel, John (NIH) [E] [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Erhardt, William (HHS/IOS) [b6]; Leifer, Eric (NIH/NHLBI) [E] [b6]; Scott Berry [b6]; Wright, Clinton (NIH/NINDS) [E] [b6]; Douglas, David (HHS/IOS) [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Bugin, Kevin (FDA/CDER) [b6]; Thomas Stock [b6]; Stock, Thomas (HHS/IOS) [b6]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Adrian Hernandez, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Springer, Jessica (NIH/NCATS) [E] [b6]; Lindsell, Chris [b6]; David Boulware [b6]; Collins, Sean P [b6]; Shotwell, Matthew Stephen [b6]; Brown, Samuel [b6]; Thompson, Taylor [b6]; Wholley, David (FNIH) [T] [b6]; Chen, Helen [qingchen@deloitte.com]; Boucher, Cynthia (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Eric Hughes [b6]; Dana Carluccio [b6]; Rose Li Central Account [b6]; Parker, CAPT Sheri (HHS/IOS) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Lawlor, Ciarán [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Punturiert, Antonello (NIH/NHLBI) [E] [b6]; Groesch, Mary (NIH/NHLBI) [E] [b6]; Shipp, Allan (NIH/NHLBI) [E] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Nayak, Seema (NIH/NIAID) [E] [b6]; Ramakrishnan, Raahul [b6]; Lerner, Andrea (NIH/NIAID) [E] [b6]; Embry, Alan (NIH/NIAID) [E] [b6]; Birgit Grund [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

CC:

Start: 8/27/2021 12:30:00 PM
End: 8/27/2021 2:00:00 PM

Recurrence: (none)

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dr Susanna Naggie, M.D. [b6]; Lundgren, Jens [b6]; Neaton, Jim [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; McNay, Laura (NIH/NIAID) [E] [b6]; Grund, Birgit [b6]; Judy Currier [b6]; David Douglas [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Michael Hughes [b6]; Kindzelski, Andrei (NIH/NHLBI) [E] [b6]; Hochman, Judith [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; LaVange, Lisa M [b6]; Beigel, John (NIH) [E] [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Erhardt, William (HHS/IOS) [b6];

Leifer, Eric (NIH/NHLBI) [E] [b6]; Scott Berry [b6]; Wright, Clinton (NIH/NINDS) [E] [b6]; Douglas, David (HHS/IOS) [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Bugin, Kevin (FDA/CDER) [b6]; Thomas Stock [b6]; Stock, Thomas (HHS/IOS) [b6]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Adrian Hernandez, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Springer, Jessica (NIH/NCATS) [E] [b6]; Lindsell, Chris [b6]; David Boulware [b6]; Collins, Sean P [b6]; Shotwell, Matthew Stephen [b6]; Brown, Samuel [b6]; Thompson, Taylor [b6];

CC: Wholley, David (FNIH) [T] [b6]; Chen, Helen [qingchen@deloitte.com]; Boucher, Cynthia (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Eric Hughes [b6]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Parker, CAPT Sheri (HHS/IOS) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Lawlor, Ciarán [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [b6]; Groesch, Mary (NIH/NHLBI) [E] [b6]; Shipp, Allan (NIH/NHLBI) [E] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Nayak, Seema (NIH/NIAID) [E] [b6]; Ramakrishnan, Raahul [b6]; Lerner, Andrea (NIH/NIAID) [E] [b6]; Embry, Alan (NIH/NIAID) [E] [b6]; Birgit Grund [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Start: 9/24/2021 12:30:00 PM
End: 9/24/2021 2:00:00 PM

Recurrence: (none)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 12/16/2020 4:39:45 PM

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [p] [b6]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Dr Susanna Naggie, M.D. [b6]; Adrian Hernandez, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Nakela Cook [b6]; Penny Mohr [b6]; Brown, Samuel [b6]

CC: Chen, Helen [qingchen@deloitte.com]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Sorosa, Alex [asorosa@deloitte.com]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Nasr, Hana [hanasr@deloitte.com]; [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]

Subject: ACTIV-2/3/6 Trial Oversight Committee Meeting

Attachments: Untitled Attachment; Untitled Attachment; Canceled: ACTIV-2/3 Trial Oversight Committee Meeting; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; ACTIV-2/3/6 Trial Oversight Committee Meeting; Untitled Attachment; Untitled Attachment; Untitled Attachment; ACTIV-2/3/6 Trial Oversight Committee Meeting, Untitled Attachment, Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: <https://fnih.zoom.us> [b6]

Start: 1/6/2021 8:00:00 PM

End: 1/6/2021 9:00:00 PM

Show Time As: Busy

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Erhardt, Bill (NIH/NIAID) [C], Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E], Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER), Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Dr Susanna Naggie, M.D.; Adrian Hernandez, M.D.; Dunsmore, Sarah (NIH/NCATS) [E]; Nakela Cook; Penny Mohr; Brown, Samuel

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS), Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]; Kurilla, Michael (NIH/NCATS) [E]

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]

CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana

[hanasr@deloitte.com]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]

Start: 1/6/2021 8:00:00 PM

End: 1/6/2021 9:00:00 PM

Recurrence: (none)

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]

CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfc346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana [hanasr@deloitte.com]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Vogel, Susan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a18354e56c6c45d5b4a9701770890c81-svogel]; Segal Raim, Sharon (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fec017d4c0f44cea96f9b89b4138b02d-segalsb]; Teitelbaum, Marc (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=834d13932b0b4bf6b6daa48ad6e052aa-teitelbaum]; Delph, Yvette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=862fc0b574d541f985209fca80451b64-ydelph.comc]

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210113.pdf

Start: 1/13/2021 8:00:00 PM
End: 1/13/2021 9:00:00 PM

Recurrence: (none)

Required Attendees: Adam, Stacey (FNIH) [T]; Wholley, David (FNIH) [T]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Read, Sarah (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Neaton, Jim; Lundgren, Jens; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Woodcock, Janet (FDA/CDER); Bozzette, Sam (NIH/NCATS) [E]; Lane, Cliff (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]

Optional Attendees: Chen, Helen; Bugin, Kevin (FDA/CDER); Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; Carver, Trea (NIH) [C]; Vogel, Susan (NIH/NIAID) [E]; Segal Raim, Sharon (NIH) [E]; Teitelbaum, Marc (NIH) [C]; Delph, Yvette

Dear ACTIV-2/3 TOC Members,

Please find attached the slides for today's meeting.

Thanks,
Stacey

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To: Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Bozette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozettesaa]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Oilmann Saphire [REDACTED]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
 CC: Nasr, Hana [hanasr@deloitte.com]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Chen, Helen
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: Canceled: ACTIV-2/3 Trial Oversight Committee Meeting

Start: 1/20/2021 5:00:00 AM

End: 1/21/2021 5:00:00 AM

Show Time As: Free

Recurrence: (none)

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Neaton, Jim; Lundgren, Jens; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Dear ACTIV-2/3 TOC Members,

Per our email discussion, we will be canceling this meeting due to many of our federal colleagues being off for the federal holiday, and because we can likely keep things moving via email this week. Thank you all for your quick responses and your flexibility.

Thanks,
Stacey

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210224.pdf

Start: 2/24/2021 8:00:00 PM
End: 2/24/2021 9:00:00 PM

Recurrence: (none)

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Neaton, Jim; Lundgren, Jens; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Lara Hosey; Sorosa, Alex; Chen, Helen; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Dear ACTIV-2/3 TOC,

Please find attached the slides for today.

Thanks,
Stacey

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Oilmann Saphire [b6] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]

CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana

[hanasr@deloitte.com]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]

Start: 3/3/2021 8:00:00 PM

End: 3/3/2021 9:00:00 PM

Recurrence: (none)

To: Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbelding, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Adrian Hernandez, M.D. [b6]; Dr Susanna Naggie, M.D. [b6]; Lindsell, Chris [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6];

CC: Chen, Helen [qingchen@deloitte.com]; Sorosa, Alex [asorosa@deloitte.com]; Harrigan, Rachel (HHS/IOS) [b6]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Nasr, Hana [hanasr@deloitte.com]; [b6];

Subject: ACTIV-2/3/6 Trial Oversight Committee Meeting

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210310.pdf

Start: 3/10/2021 8:00:00 PM

End: 3/10/2021 9:30:00 PM

Show Time As: Busy

Recurrence: (none)

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Adrian Hernandez, M.D.; Dr Susanna Naggie, M.D.; Lindsell, Chris; Kurilla, Michael (NIH/NCATS) [E]; [b6];

Optional Attendees: Chen, Helen Q., Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6];

Dear ACTIV-2, -3, and -6 Teams and TOC,

Please find attached the slides for today's meeting.

Thanks,
Stacey

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]

CC: Chen, Helen [qingchen@deloitte.com]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Sorosa, Alex [asorosa@deloitte.com]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Nasr, Hana [hanasr@deloitte.com]; [b6]; Bethany Stokes [b6]

Start: 3/17/2021 7:00:00 PM
End: 3/17/2021 8:00:00 PM

Recurrence: (none)

Required Attendees: Adam, Stacey (FNIH) [T]; Wholley, David (FNIH) [T]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; [b6]; Woodcock, Janet (FDA/OC)

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]; Erhardt, Bill (NIH/NIAID) [C]; Bethany Stokes

To: Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6];

CC: Chen, Helen [qingchen@deloitte.com]; Sorosa, Alex [asorosa@deloitte.com]; Harrigan, Rachel (HHS/IOS) [b6]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Nasr, Hana [hanasr@deloitte.com]; Li, Jonathan, M.D. [b6]; Fletcher, Courtney V [b6];

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210324.pdf

Start: 3/24/2021 7:00:00 PM
End: 3/24/2021 8:00:00 PM

Recurrence: (none)

Required Attendees: Wholley, David (FNIH) [T], Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E], Lane, Cliff (NIH/NIAID) [E], Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Neaton, Jim; Lundgren, Jens; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Erhardt, Bill (NIH/NIAID) [C]

Optional Attendees: Chen, Helen; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]; Li, Jonathan, M.D.; Fletcher, Courtney V

Dear ACTIV-2/3/6 TOC,

Please find attached the slides for today's meeting.

Thanks,
Stacey

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To: Erhardt, Bill (NIH/NIAID) [C] [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Erhardt, Bill (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7145bbcafb64529a0e0ea73b278dca5-erhardtwa]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001 um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Weiss, Carol (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44273df1fd04686b82b578878db2f67-Carol.Weiss]; Erlandson, Karl (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6065f551f0224ed280110d770df55185-karl.erland]; Dr Susanna Naggie, M.D. [b6]; Adrian Hernandez, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmores]; Nakela Cook [b6]; Penny Mohr [b6];

CC: Chen, Helen [qingchen@deloitte.com]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS)

b6

Sorosa, Alex [asorosa@deloitte.com]; Erhardt, William (HHS/IOS)
; Melencio, Cheryl (FNIH) [T] **b6**; Harrigan, Rachel (HHS/IOS)
; Nasr, Hana [hanasr@deloitte.com]; Chen, Helen [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de];
Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen
b6; Lisbeth Jørgensen **b6**; Rose Li Central Account
[FNIH@roseliassociates.com]; Dana Carluccio **b6**; Church, Elizabeth (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Erhardt, William
(HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina
b6; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1];
b6 Bentley, Lisa Marie (OS/ASPR/SIIM) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=80189a18d6014c6cbd0df08569aad10f-LisaMarie.B]

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210331.pdf

Start: 3/31/2021 7:00:00 PM

End: 3/31/2021 8:00:00 PM

Recurrence: (none)

Required Attendees: Erhardt, Bill (NIH/NIAID) [C], Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA)
(CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily
(NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith,
David; Kim, Peter (NIH/NIAID) [E]; **b6**; Higgs, Elizabeth (NIH/NIAID) [E];
Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Weiss, Carol (FDA/CBER); Erlandson, Karl
(OS/ASPR/BARDA); Dr Susanna Naggie, M.D., Adrian Hernandez, M.D.; Dunsmore, Sarah (NIH/NCATS) [E]; Nakela
Cook; Penny Mohr

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central
Account, Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt,
William (HHS/IOS), Melencio, Cheryl (FNIH) [T], Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel
(HHS/IOS); Nasr, Hana; **b6**; Bentley, Lisa Marie (OS/ASPR/SIIM)

Dear TOC Members,

Please see attached the slides for today.

Thanks,
Stacey

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b6

To: Bozzette, Sam (NIH/NCATS) [E] [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; [b6]; Wholley, David (FNIH) [T] [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbeiding, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Carrier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Dr Susanna Naggie, M.D. [b6]; Adrian Hernandez, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Nakela Cook [b6]; Penny Mohr [b6]; Woodcock, Janet (FDA/OC) [b6]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]

CC: Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Chen, Helen [qingchen@deloitte.com]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Sorosa, Alex [asorosa@deloitte.com]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Nasr, Hana [hanasr@deloitte.com]; Kurilla, Michael (NIH/NCATS) [E] [b6]

Subject: ACTIV-2/3/6 Trial Oversight Committee Meeting

Start: 4/21/2021 7:00:00 PM

End: 4/21/2021 8:00:00 PM

Recurrence: (none)

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Woodcock, Janet (FDA/OC); Erhardt, Bill (NIH/NIAID) [C]; Wholley, David (FNIH) [T]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeiding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Carrier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Dr Susanna Naggie, M.D.; Adrian Hernandez, M.D.; Dunsmore, Sarah (NIH/NCATS) [E]; Nakela Cook; Penny Mohr

Optional Attendees: Chen, Helen Q., Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]; Kurilla, Michael (NIH/NCATS) [E]

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Dr Susanna Naggie, M.D. [b6]; Adrian Hernandez, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Penny Mohr [b6]; Nakela Cook [b6]; Brown, Samuel [b6]

CC: Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Chen, Helen [qingchen@deloitte.com]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Sorosa, Alex [asorosa@deloitte.com]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Nasr, Hana [hanasr@deloitte.com]; Kurilla, Michael (NIH/NCATS) [E] [b6]

Start: 4/28/2021 7:00:00 PM
End: 4/28/2021 8:00:00 PM

Recurrence: (none)

Required Attendees: Nakela Cook; Erhardt, Bill (NIH/NIAID) [C]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Dr Susanna Naggie, M.D.; Adrian Hernandez, M.D.; Dunsmore, Sarah (NIH/NCATS) [E]; Penny Mohr; Brown, Samuel

Optional Attendees: Kurilla, Michael (NIH/NCATS) [E]; Chen, Helen Q., Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]

To: Bozzette, Sam (NIH/NCATS) [E] [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Davey Smith [b6]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbelding, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [Peter.Stein@fda.hhs.gov]; Judy Currier [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Dr Susanna Naggie, M.D. [b6]; Adrian Hernandez, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Penny Mohr [b6]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Nakela Cook [b6]

CC: Chen, Helen [qingchen@deloitte.com]; Sorosa, Alex [asorosa@deloitte.com]; Harrigan, Rachel (HHS/IOS) [b6]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Nasr, Hana [hanasr@deloitte.com]; Lindsell, Chris [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210407.pdf

Start: 4/7/2021 7:00:00 PM

End: 4/7/2021 8:00:00 PM

Recurrence: (none)

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Nakela Cook; Erhardt, Bill (NIH/NIAID) [C]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Dr Susanna Naggie, M.D.; Adrian Hernandez, M.D.; Dunsmore, Sarah (NIH/NCATS) [E]; Penny Mohr

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]; Lindsell, Chris

Dear ACTIV-2/3/6 TOC Members,

Please find attached the slides for today's meeting.

Thanks,
Stacey

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbelding, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Dr Susanna Naggie, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Nakela Cook [b6]; Penny Mohr [b6]; Adrian Hernandez, M.D. [b6]; Brown, Samuel [b6]

CC: Chen, Helen [qingchen@deloitte.com]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Sorosa, Alex [asorosa@deloitte.com]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Nasr, Hana [hanasr@deloitte.com]; [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]

Start: 6/2/2021 7:00:00 PM

End: 6/2/2021 8:00:00 PM

Recurrence: (none)

Required Attendees: Adrian Hernandez, M.D.; Erhardt, Bill (NIH/NIAID) [C]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Dr Susanna Naggie, M.D.; Dunsmore, Sarah (NIH/NCATS) [E]; Nakela Cook; Penny Mohr; Brown, Samuel

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]; Kurilla, Michael (NIH/NCATS) [E]

To: Bozzette, Sam (NIH/NCATS) [E] [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbelding, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Dr Susanna Naggie, M.D. [b6]; Adrian Hernandez, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Nakela Cook [b6]; Penny Mohr [b6]; Brown, Samuel [b6]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]

CC: Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Chen, Helen [qingchen@deloitte.com]; Sorosa, Alex [asorosa@deloitte.com]; Harrigan, Rachel (HHS/IOS) [b6]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Nasr, Hana [hanasr@deloitte.com]; Kurilla, Michael (NIH/NCATS) [E] [b6]

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210414.pdf

Start: 4/14/2021 7:00:00 PM
End: 4/14/2021 8:00:00 PM

Recurrence: (none)

Required Attendees: Erhardt, Bill (NIH/NIAID) [C]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Dr Susanna Naggie, M.D.; Adrian Hernandez, M.D.; Dunsmore, Sarah (NIH/NCATS) [E]; Nakela Cook; Penny Mohr; Brown, Samuel

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]; Kurilla, Michael (NIH/NCATS) [E]

Dear ACTIV-2/3/6 TOC,

Please find attached the slides for today's meeting.

Thanks,
Stacey

Join Zoom Meeting
[https://fnih.zoom.us/j/\[b6\]](https://fnih.zoom.us/j/[b6])

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Passcode: **b6**

Find your local number: <https://fnih.zoom.us> **b6**

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Dr Susanna Naggie, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Nakela Cook [b6]; Penny Mohr [b6]; Brown, Samuel [b6]; Adrian Hernandez, M.D. [b6]

CC: Chen, Helen [qingchen@deloitte.com]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Sorosa, Alex [asorosa@deloitte.com]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaa9e06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Nasr, Hana [hanasr@deloitte.com]; [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]

Start: 5/12/2021 7:00:00 PM

End: 5/12/2021 8:00:00 PM

Recurrence: (none)

Required Attendees: Erhardt, Bill (NIH/NIAID) [C], Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E], Read, Sarah (NIH/NIAID) [E], Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Dr Susanna Naggie, M.D.; Adrian Hernandez, M.D.; Dunsmore, Sarah (NIH/NCATS) [E]; Nakela Cook; Penny Mohr; Brown, Samuel

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]; Kurilla, Michael (NIH/NCATS) [E]

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Erhardt, Bill (NIH/NIAID) [C] [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbelding, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Dr Susanna Naggie, M.D. [b6]; Dunsmore, Sarah (NIH/NCATS) [E] [b6]; Nakela Cook [b6]; Penny Mohr [b6]; Brown, Samuel [b6]; Adrian Hernandez, M.D. [b6]

CC: Chen, Helen [qingchen@deloitte.com]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Sorosa, Alex [asorosa@deloitte.com]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Nasr, Hana [hanasr@deloitte.com]; [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]

Start: 5/26/2021 7:00:00 PM

End: 5/26/2021 8:00:00 PM

Recurrence: (none)

Required Attendees: Erhardt, Bill (NIH/NIAID) [C]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Dr Susanna Naggie, M.D.; Adrian Hernandez, M.D.; Dunsmore, Sarah (NIH/NCATS) [E]; Nakela Cook; Penny Mohr; Brown, Samuel

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]; Kurilla, Michael (NIH/NCATS) [E]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 3/2/2021 3:56:32 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]

Subject: ACTIV "War Room" Calls

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: Dial-in: Passcode:

Start: 3/19/2021 12:00:00 PM

End: 3/19/2021 12:30:00 PM

Show Time As: Busy

Recurrence: Weekly
every Friday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Parker, Ashley (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Rutter, Joni (NIH/NCATS) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Carver, Trea (NIH) [C]; Sepulveda, Dorina (FNIH) [T]; Dimishkov, Roxanne (NIH/NHLBI) [C]

Extending Friday calls through May 14, 2021

Dial-in:

Passcode:

Dr. Tabak as Leader:

To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]

CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]

Start: 3/19/2021 12:00:00 PM
End: 3/19/2021 12:30:00 PM

Recurrence: (none)

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/26/2021 1:40:25 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210326.pptx
Attachments: ACTIV Daily Update 20210326.pptx

Please find attached slides for tomorrow morning's war room, Friday March 26.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/2/2021 10:38:43 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: 20210330_Note on Variant Nomenclature
Attachments: 20210330_Note on Variant Nomenclature.docx

An additional document for this morning's 4/2/21 war room, forwarded by Joe Menetski

From: Lane, Cliff (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2D7E368A3137473BBCE161547A82F2DE-CLANE]
Sent: 4/2/2021 6:05:32 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: Re: ACTIV Daily Update 20210402.pptx
Attachments: Quanterix April 2021 final.pptx

+ a few slides on some of the preliminary data from the Quanterix antigen assay.

Cliff

From: "Wholley, David (FNIH) [T]" [b6]
Date: Thursday, April 1, 2021 at 6:17 PM
To: "Collins, Francis (NIH/OD) [E]" [b6], Lawrence Tabak [b6] "Lane, Cliff (NIH/NIAID) [E]" [b6], "Freire, Maria (FNIH) [T]" [b6] "Rutter, Joni (NIH/NCATS) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6] "Anderson, James (NIH/OD) [E]" [b6] "Patterson, Amy (NIH/NHLBI) [E]" [b6]
Subject: ACTIV Daily Update 20210402.pptx

Here are the slides for tomorrow's war room, Friday April 2.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/2/2021 1:16:15 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210402.pptx
Attachments: ACTIV Daily Update 20210402.pptx

Here are the slides for tomorrow's war room, Friday April 2.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 3/2/2021 3:53:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]

Subject: ACTIV "War Room" Calls

Attachments: Untitled Attachment; Untitled Attachment

Location: Dial-in: Passcode:

Start: 3/17/2021 12:00:00 PM

End: 3/17/2021 12:30:00 PM

Show Time As: Busy

Recurrence: Weekly
every Wednesday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Anderson, James (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Rutter, Joni (NIH/NCATS) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Carver, Trea (NIH) [C]; Sepulveda, Dorina (FNIH) [T]; Dimishkov, Roxanne (NIH/NHLBI) [C]

Extending Wednesday calls through May 12, 2021

Dial-in:

Passcode:

Dr. Tabak as Leader:

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/17/2021 2:30:34 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: ACTIV Daily Update 20210317.pptx
Attachments: ACTIV Daily Update 20210317.pptx

Here are slides for tomorrow morning's war room, Wednesday March 17. 

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]

CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]

Attachments: ACTIV Daily Update 20210324.pptx

Start: 3/24/2021 12:00:00 PM

End: 3/24/2021 12:30:00 PM

Recurrence: (none)

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Anderson, James (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Rutter, Joni (NIH/NCATS) [E]; Santos, Michael (FNIH) [T]

Extending Wednesday calls through May 12, 2021

Dial-in:

Passcode:

Dr. Tabak as Leader:

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/24/2021 1:35:04 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: ACTIV Daily Update 20210324.pptx
Attachments: ACTIV Daily Update 20210324.pptx

Please see attached the slides for tomorrow morning's war room, Wednesday March 24.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/15/2021 1:40:01 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210315.pptx
Attachments: ACTIV Daily Update 20210315.pptx

Attached are slides for tomorrow morning's war room, Monday March 15.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/22/2021 2:32:31 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210322.pptx
Attachments: ACTIV Daily Update 20210322.pptx

Please see attached slides for tomorrow morning's war room, Monday March 22.

From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 10/16/2020 6:07:30 PM
To: Hawk, Harrison [hhawk@deloitte.com]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA) : [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; [b6] FNIH [fnih@roseliassociates.com]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; [b6] [b6]
CC: Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]
Subject: ACTIV Preclinical - Post-Acute Sequelae of SARS-CoV-2 Infection (PASC) Discussion
Attachments: Untitled Attachment; Canceled: ACTIV Preclinical - In Vivo Strategy ; Canceled: ACTIV Preclinical - In Vivo Strategy ; Untitled Attachment; ACTIV Preclinical - Long Hauler Discussion; Untitled Attachment
Location: https://deloitte.zoom.us/j/[b6]
Start: 10/23/2020 3:00:00 PM
End: 10/23/2020 4:00:00 PM
Show Time As: Busy

Recurrence: (none)

Hi all,

Rescheduling this series due to a conflict with another recurring meeting for many of our attendees.

Best,
Harrison

Join Meeting

Password:

Phone one-tap:

b6

Join by Telephone

Dial:

b6

Meeting ID:

b6

Password:

International numbers

Zoom technology includes options for recording a meeting. If a meeting is being recorded, an audio and/or visual warning will be provided when you join a recorded meeting. A warning will also be provided if recording commences after you have joined the meeting. If you continue to participate in the meeting following these warnings, your participation will serve as your express consent to such recording.

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To: Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Hawk, Harrison [hhawk@deloitte.com]; Young, John [redacted] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; [redacted] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [redacted] CIV USARMY MEDCOM USAMRIID (USA) [redacted] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [redacted]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [redacted]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]

Start: 10/23/2020 2:00:00 PM

End: 10/23/2020 3:00:00 PM

Recurrence: (none)

Hi all,

Please find the agenda for tomorrow's meeting below. If you have any questions or wish to add items, let us know. We will likely be giving some time back.

Thanks!
Harrison

Agenda Topic	Duration	Facilitator
Updates on Small animal model field guide development	10 mins	Isis Kanevsky Cat Lutz
Updates on offline NHP field guide work	10 mins	Nancy Haigwood Jay Rappaport

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[b6]
L CIV USARMY MEDCOM USAMRIID (USA) [b6]

[b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]

Subject: Canceled: ACTIV Preclinical - In Vivo Strategy

Start: 12/18/2020 3:00:00 PM

End: 12/18/2020 4:00:00 PM

Show Time As: Free

Recurrence: (none)

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Subject: Canceled: ACTIV Preclinical - In Vivo Strategy

Start: 1/1/2021 3:00:00 PM

End: 1/1/2021 4:00:00 PM

Show Time As: Free

Recurrence: (none)

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CC: Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]

Attachments: image001.png; image003.png; image002.png; image001.png

Start: 1/29/2021 4:00:00 PM
End: 1/29/2021 5:00:00 PM

Recurrence: (none)

Hi all,

Please see below for the agenda for this morning's meeting.

Agenda Topic	Duration	Facilitator
Updates on offline NHP field guide work	5 mins	Nancy Haigwood Jay Rappaport
Updates on BEI viral stock production (as needed)	5 mins	Clint Florence
Discuss possible topics for small animal models and NHP panels	30 minutes	Christine Colvis Joe Menetski
Align on action items and next steps	5 mins	Sarah Connelly Joe Menetski

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[b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp];
[b6] Nancy Haigwood
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USARMY MEDCOM USAMRIID (USA) [b6]; Charette, Marc (NIH/NHLBI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E]
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D
[b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]
[b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connolly, Sarah
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fessel.jp];

CC: [b6]
Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]

Subject: ACTIV Preclinical - Long Hauler Discussion

Location: <https://deloitte.zoom.us/j/92036206000> [b6]

Start: 2/26/2021 4:00:00 PM

End: 2/26/2021 5:00:00 PM

Show Time As: Busy

Recurrence: (none)

Updating title to reflect new focus on long-term sequelae of COVID-19

Hi all,

Rescheduling this series due to a conflict with another recurring meeting for many of our attendees.

Best,
Harrison

APAR0000000261

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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D
 [b6] Young, John [b6]; Fessel, Josh
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 [b6] Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6]; Charette, Marc (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [b6]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; [b6]; FNIH
 [fnih@roseliassociates.com]; [b6] Chad Roy
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=431f5cdf4ab4b018b2bdb18bf47e913-croy.tulane]; [b6]
CC: Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]

Start: 3/26/2021 3:00:00 PM

End: 3/26/2021 4:00:00 PM

Recurrence: (none)

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 11/30/2020 1:04:36 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]

Subject: ACTIV Call "War Room"

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment, Untitled Attachment; Untitled Attachment; Untitled Attachment, Untitled Attachment; Untitled Attachment, Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: Dial-in: Passcode:

Start: 12/7/2020 1:00:00 PM

End: 12/7/2020 1:30:00 PM

Show Time As: Busy

Recurrence: Weekly

Occurs every Monday from 8:00 AM to 8:30 AM effective 12/7/2020 until 3/8/2021.

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Rutter, Joni (NIH/NCATS) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Carver, Trea (NIH) [C]; Sepulveda, Dorina (FNIH) [T]; Patterson, Amy (NIH/NHLBI) [E]; Adam, Stacey (FNIH) [T]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Freire, Maria (FNIH) [T]

Extending to end of December

Dial-in:

Passcode:

Dr. Tabak as Leader:

To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]

CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Adam, Stacey (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dimishkov, Roxanne
 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Gibbons, Gary
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]

Attachments: ACTIV Daily Update 20201215v3.pptx

Start: 12/15/2020 1:00:00 PM
End: 12/15/2020 1:30:00 PM
Show Time As: Busy

Recurrence: (none)

Required Attendees: Melencio, Cheryl (FNIH) [T]; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E];
Attendees: Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Lane, Cliff
 (NIH/NIAID) [E]
Optional Attendees: Freire, Maria (FNIH) [T]; Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi
 (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Carver, Trea
 (NIH) [C]; Sepulveda, Dorina (FNIH) [T]; Patterson, Amy (NIH/NHLBI) [E]; Adam, Stacey (FNIH) [T]; Dimishkov,
 Roxanne (NIH/NHLBI) [C]; Gibbons, Gary (NIH/NHLBI) [E]

Extending to end of December

Dial-in:
Passcode:

Dr. Tabak as Leader:

Discussion yesterday with AdVent Health. Discuss contracting there. Stacey is working through the contacts (Tony, Amy)

IDEA sights connected with ACTIV trial teams.

Escape of resistance – slide to talk about their accomplishments. Met with several companies. Identify a data source network. Find a way to integrate; analysis visual tools. What is the database and centralized repository agreed on.

SAB Feb 1st to be ready for clinical tx WG.

Lessons learned and budget discussion.

Activate GSK/Vir this week.

ACTIV 4c was open label and converted to a; needed additional monies and just received \$\$ this week and has been a major hold up. Apixadan launch next week.

To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]

CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH)
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gibbons, Gary (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]

Start: 12/21/2020 1:00:00 PM
End: 12/21/2020 1:30:00 PM

Recurrence: (none)

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Carver, Trea (NIH) [C]; Sepulveda, Dorina (FNIH) [T]; Patterson, Amy (NIH/NHLBI) [E]; Adam, Stacey (FNIH) [T]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Freire, Maria (FNIH) [T]; Gibbons, Gary (NIH/NHLBI) [E]

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Adam, Stacey (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dimishkov, Roxanne
(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Freire, Maria (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Patterson, Amy
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]

Attachments: RE: ACTIV Daily Update 20210104.pptx; ACTIV Daily Update 20210104.pptx

Start: 1/4/2021 1:00:00 PM
End: 1/4/2021 1:30:00 PM

Recurrence: (none)

Extending to end of December

Dial-in: [b6]
Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Anderson, James (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]
Sent: 1/4/2021 1:29:28 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: RE: ACTIV Daily Update 20210104.pptx
Attachments: NIH SARS-CoV-2 Antiviral Therapeutics Summit Report_CLEAN.pdf

Attached is late draft of the antiviral target report cleared by Francis, Chris and Hugh Auchincloss. We will get it public this week.

Jim

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, January 4, 2021 7:37 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]
Subject: ACTIV Daily Update 20210104.pptx

Please see slides for today's war room call, Monday January 4, 2021.

To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]

CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Adam, Stacey (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dimishkov, Roxanne
 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Freire, Maria (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Menetski, Joseph (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]

Attachments: ACTIV Daily Update 20210111.pptx; War Room ACTIV call 01_11_21.docx

Start: 1/11/2021 1:00:00 PM
End: 1/11/2021 1:30:00 PM

Recurrence: (none)

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Carver, Trea (NIH) [C]; Sepulveda, Dorina (FNIH) [T]; Patterson, Amy (NIH/NHLBI) [E]; Adam, Stacey (FNIH) [T]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Freire, Maria (FNIH) [T]; Menetski, Joseph (FNIH) [T]

Extending to end of December

Dial-in:
Passcode:

Dr. Tabak as Leader:

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/11/2021 3:57:51 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: ACTIV Daily Update 20210111.pptx
Attachments: ACTIV Daily Update 20210111.pptx

Attached are slides for tomorrow morning's war room, Monday January 11. Please note we will be joined by Joe Menetski to discuss the pandemic preparedness effort.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/25/2021 12:31:19 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210125.pptx
Attachments: ACTIV Daily Update 20210125.pptx

Please see attached slides for this morning's war room, Monday January 25.

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 1/24/2021 7:47:47 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab3c42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: Global Consortium
Attachments: 210122_Global and U.S. Pandemic Genomics Platform_Rockefeller Foundation_vFINAL.pdf

Hi all,

See below and attached. It's not clear to me that the Rockefeller Foundation is the right organization to lead the proposed global pandemic surveillance effort, and their proposal overlaps rather heavily with our ACTIV mutation tracking and functional analysis (aka COVER) program. I've responded to Raj and Rick, asking for a call this coming week. But perhaps we can discuss this at tomorrow's War Room.

Francis

From: Fauci, Anthony (NIH/NIAID) [E] [b6]
Sent: Saturday, January 23, 2021 4:46 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: FW: Global Consortium

Francis:

I am attaching a proposal from The Rockefeller Foundation that Rick Klausner and Raj Shah have discussed with me. It calls for a Consortium for Global Pandemic Surveillance and Preparedness. Given our discussions of the role of NIH/ACTIV in the CIG, I was wondering if you think the NIH might have a role in this consortium.

Best regards,

Tony

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 2/1/2021 3:39:57 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210201.pptx
Attachments: ACTIV Daily Update 20210201.pptx

Please see slides attached for tomorrow's war room call, Monday February 1.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 2/8/2021 12:28:37 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210208.pptx
Attachments: ACTIV Daily Update 20210208.pptx

Please find attached the slides for this morning's war room, Monday February 8.

To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]

CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba85249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]

Attachments: ACTIV Daily Update 20210301.pptx

Start: 3/1/2021 1:00:00 PM
End: 3/1/2021 1:30:00 PM

Recurrence: (none)

Extending to end of December

Dial-in:
Passcode:

Dr. Tabak as Leader:

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/1/2021 3:16:33 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210301.pptx
Attachments: ACTIV Daily Update 20210301.pptx

Attached please find war room slides for tomorrow's meeting, Monday March 1.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/8/2021 11:50:05 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210308.pptx
Attachments: ACTIV Daily Update 20210308.pptx

Attached are slides for this morning's war room, Monday March 8.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/16/2020 4:39:45 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbelding, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Chen, Helen [qingchen@deloitte.com]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Sorosa, Alex [asorosa@deloitte.com]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Nasr, Hana [hanasr@deloitte.com]; [b6]
Subject: ACTIV-2/3 Trial Oversight Committee Meeting
Attachments: Untitled Attachment; Untitled Attachment; Canceled: ACTIV-2/3 Trial Oversight Committee Meeting; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; ACTIV-2/3/6 Trial Oversight Committee Meeting; Untitled Attachment
Location: https://fnih.zoom.us/j/[b6]
Start: 1/6/2021 8:00:00 PM
End: 1/6/2021 9:00:00 PM
Show Time As: Busy
Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM
Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Neaton, Jim; Lundgren, Jens; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; [b6]
Optional Attendees: Chen, Helen; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]; Erhardt, Bill (NIH/NIAID) [C]

Stacey Adam is inviting you to a scheduled Zoom meeting.

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US (San Jose)
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Passcode: **b6**

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]

CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana

[hanasr@deloitte.com]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]

Start: 1/6/2021 8:00:00 PM

End: 1/6/2021 9:00:00 PM

Recurrence: (none)

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]

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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: Canceled: ACTIV-2/3 Trial Oversight Committee Meeting

Start: 1/20/2021 5:00:00 AM

End: 1/21/2021 5:00:00 AM

Show Time As: Free

Required Attendees:	Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Neaton, Jim; Lundgren, Jens; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]
Optional Attendees:	Chen, Helen; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex; Erhardt, William (HHS/IOS); Meienicio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Per our email discussion, we will be canceling this meeting due to many of our federal colleagues being off for the federal holiday, and because we can likely keep things moving via email this week. Thank you all for your quick responses and your flexibility.

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]

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[hanasr@deloitte.com]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210203.pdf

Start: 2/3/2021 8:00:00 PM
End: 2/3/2021 9:00:00 PM

Recurrence: (none)

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Neaton, Jim; Lundgren, Jens; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Sorosa, Alex; Chen, Helen; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Dear All,

Please find attached the slides for today's meeting.

Thanks,
Stacey

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]

CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [dana.carluccio@roseliassociates.com]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana [hanasr@deloitte.com]; Kelly Beazley [b6]; Sorosa, Alex

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Oilmann Saphire [b6] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]

CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Reich, Colleen [b6] Lisbeth Jørgensen [b6] Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6] Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6] Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana [hanasr@deloitte.com]; Lara Hosey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3259a2a75c284dcf9123b0f0ae2cad62-LaraHosey]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210224.pdf

Start: 2/24/2021 8:00:00 PM
End: 2/24/2021 9:00:00 PM

Recurrence: (none)

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; Neaton, Jim; Lundgren, Jens; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Lara Hosey; Sorosa, Alex; Chen, Helen; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Dear ACTIV-2/3 TOC,

Please find attached the slides for today.

Thanks,
Stacey

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Oilmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]

CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [dana.carluccio@roseliassociates.com]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana

[hanasr@deloitte.com]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]

Start: 3/3/2021 8:00:00 PM

End: 3/3/2021 9:00:00 PM

Recurrence: (none)

To: Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Adrian Hernandez, M.D. [b6]; Dr Susanna Naggie, M.D. [b6]; Lindsell, Chris [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6];

CC: Chen, Helen [qingchen@deloitte.com]; Sorosa, Alex [asorosa@deloitte.com]; Harrigan, Rachel (HHS/IOS) [b6]; Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Nasr, Hana [hanasr@deloitte.com]; [b6];

Subject: ACTIV-2/3/6 Trial Oversight Committee Meeting

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20210310.pdf

Start: 3/10/2021 8:00:00 PM

End: 3/10/2021 9:30:00 PM

Show Time As: Busy

Recurrence: (none)

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Adrian Hernandez, M.D.; Dr Susanna Naggie, M.D.; Lindsell, Chris; Kurilla, Michael (NIH/NCATS) [E] [b6];

Optional Attendees: Chen, Helen Q., Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6];

Dear ACTIV-2, -3, and -6 Teams and TOC,

Please find attached the slides for today's meeting.

Thanks,
Stacey

Join Zoom Meeting

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US (Tacoma)
US (Houston)
US (San Jose)
US (San Jose)

Meeting ID: **b6**

Passcode: **b6**

Find your local number: <https://fnih.zoom.us> **b6**

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Erbelding, Emily (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [Peter.Stein@fda.hhs.gov]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Neaton, Jim [b6]; Lundgren, Jens [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]

CC: Chen, Helen (qingchen@deloitte.com); Bugin, Kevin (FDA/CDER) [b6]; Carver, Trea (NIH) [C] [b6]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account (FNIH@roseliassociates.com); Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Sorosa, Alex (sorosa@deloitte.com); Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Nasr, Hana [hanasr@deloitte.com]; waerhardt@outlook.com; Bethany Stokes [b6]

Start: 3/17/2021 7:00:00 PM
End: 3/17/2021 8:00:00 PM

Recurrence: (none)

Required Attendees: Adam, Stacey (FNIH) [T]; Wholley, David (FNIH) [T]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; [b6]; Woodcock, Janet (FDA/OC)

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; [b6]; Erhardt, Bill (NIH/NIAID) [C]; Bethany Stokes

From: Spady, Tyrone (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=16F0D90973454F3B90364E2C171D10BD-SPADYTC]
Sent: 9/2/2020 9:46:38 PM
To: Bayha, Ryan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d5a4353cd514322a8598dbb1751ee79-bayhar]; Berger, Adam (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cfbf537ab62640ffa150a8f65241879f-bergerac]; Diggs, Susan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3bdf8cac94049dcab28d2eb5fad5137-bruffs]; Fennington, Kelly (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e2d306aa244429b0f51d365bd24a26-fenningk]; Isaacman-Beck, Jesse (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e904049e00e14f6580fee45079c23b0a-isaacmanbec]; Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]; Koniges, Ursula (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d5ae2c3139654bc0b9b95718d516310b-konigesum]; Paine, Taunton (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8d5e69b1d824f28b05d62611ec4650b-painett]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Spady, Tyrone (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16f0d90973454f3b90364e2c171d10bd-spadytc]; Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbfb5e52c31a4-tuckerjm]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Creery, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6ed3522d2c40dab248a553dad50e7b-creeryjd]
Subject: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Hi all:

IMOD has issued a call for source material (reports, websites, formal announcements, etc...) for the OD Congressional Justification narrative (see below). Some of you may have already provided your contributions. If so, please let me know. We've listed the topics where OSP might have source materials to add. Please add any relevant source material on the subjects listed below (Full doc: [OD CJ Outline](#)) to the Teams folder named "[Narrative Source Material](#)" by COB on Friday, September 4th. Let me know if you have any questions.

b5

b5

Cheers,
Tyrone

From: Landis, Erica (NIH/OD) [E]; [b6]
Sent: Tuesday, September 1, 2020 5:09 PM
To: Culhane, Ned (NIH/OD) [E]; [b6]; Hentges, Justin (NIH/OD) [E]; [b6]
Heath-Mason, Matthew (NIH/OD) [E]; [b6]; Le Fauve, Charlene (NIH/OD) [E]
[b6]; Kawazoe, Robin (NIH/OD) [E]; [b6]; Spady, Tyrone (NIH/OD) [E]
[b6]; Creery, Jessica (NIH/OD) [E]; [b6]; Noursi, Samia (NIH/OD) [E]
[b6]; Morris, Patricia (NIH/NICHD) [E]; [b6]; Luetkemeier, Erin (NIH/OD) [E]
[b6]; Klock, Kevin (FNIH) [T]; [b6]; Edghill Spano, Yvette (NIH/OD) [E]
[b6]; Espinoza, Tasha (NIH/OD) [E]; [b6]; Morris, Kathryn (NIH/OD) [E]
[b6]; Myles, Renate (NIH/OD) [E]; [b6]; Burklow, John (NIH/OD) [E]
[b6]; Peterman Cross, Wilma (NIH/OD) [E]; [b6]; Thurn, Anne (NIH/OD) [E]
[b6]; Kosub, David (NIH/OD) [E]; [b6]; Columbus, Megan (NIH/OD) [E]
[b6]; Rabin, Elise (NIH/OD) [E]; [b6]; Owens, Roland (NIH/OD) [E]
[b6]; Murray, Darryl (NIH/OD) [E]; [b6]; Shorback, Janet (NIH/OD) [E]
[b6]; Stevens, Mark (NIH/OD) [E]; [b6]; Newman, Patricia (NIH/OD) [E]
[b6]; Spencer, Elizabeth (NIH/OD) [E]; [b6]; Ekweani, Elonna (NIH/OD) [E]
[b6]; Vonkollmar, Desiree (NIH/OD) [E]; [b6]; Courchesne, Stephanie (NIH/OD)
[E]; [b6]; Fennington, Kelly (NIH/OD) [E]; [b6]; Spaniol, Erin (NIH/OD) [E]
[b6]; Baker, Rebecca (NIH/OD) [E]; [b6]
Cc: Mazzucco, Anna (NIH/OD) [E]; [b6]
Subject: Re: Request: Source material for OD CJ Narrative draft

Dear all,

Thank you to those who have already provided source material for the OD Congressional Justification narrative. If you have not had a chance to yet, please add any relevant source material on the subjects listed in the OD CJ Outline to the Teams folder named "Narrative Source Material" by **COB on Friday, September 4th**.

Please feel free to reach out with any questions you have.

Very best,
Erica

Erica G. Landis, PhD
AAAS Science & Technology Policy Fellow
Immediate Office of the Director

APAR0000000419

National Institutes of Health

A: Building 1, Room 114

P: [REDACTED]

From: "Landis, Erica (NIH/OD) [E]" [REDACTED]

Date: Monday, August 24, 2020 at 12:04 PM

To: "Culhane, Ned (NIH/OD) [E]" [REDACTED], "Hentges, Justin (NIH/OD) [E]"

[REDACTED], "Heath-Mason, Matthew (NIH/OD) [E]" [REDACTED], "Le

Fauve, Charlene (NIH/OD) [E]" [REDACTED], "Kawazoe, Robin (NIH/OD) [E]"

[REDACTED], "Spady, Tyrone (NIH/OD) [E]" [REDACTED], "Creery, Jessica (NIH/OD)

[E]" [REDACTED], "Noursi, Samia (NIH/OD) [E]" [REDACTED], "Morris, Patricia

(NIH/NICHD) [E]" [REDACTED], "Luetkemeier, Erin (NIH/OD) [E]" [REDACTED],

"Klock, Kevin (FNIH) [T]" [REDACTED], "Edghill Spano, Yvette (NIH/OD) [E]"

[REDACTED], "Espinoza, Tasha (NIH/OD) [E]" [REDACTED], "Morris, Kathryn

(NIH/OD) [E]" [REDACTED], "Myles, Renate (NIH/OD) [E]" [REDACTED], "Burklow,

John (NIH/OD) [E]" [REDACTED], "Peterman Cross, Wilma (NIH/OD) [E]"

[REDACTED], "Thurn, Anne (NIH/OD) [E]" [REDACTED], "Kosub, David (NIH/OD) [E]"

[REDACTED], "Columbus, Megan (NIH/OD) [E]" [REDACTED], "Rabin, Elise (NIH/OD)

[E]" [REDACTED], "Owens, Roland (NIH/OD) [E]" [REDACTED], "Murray, Darryl (NIH/OD)

[E]" [REDACTED], "Shorback, Janet (NIH/OD) [E]" [REDACTED], "Stevens, Mark

(NIH/OD) [E]" [REDACTED], "Newman, Patricia (NIH/OD) [E]" [REDACTED],

"Spencer, Elizabeth (NIH/OD) [E]" [REDACTED], "Ekweani, Elonna (NIH/OD) [E]"

[REDACTED], "Vonkollmar, Desiree (NIH/OD) [E]" [REDACTED], "Courchesne,

Stephanie (NIH/OD) [E]" [REDACTED], "Fennington, Kelly (NIH/OD) [E]"

[REDACTED], "Spaniol, Erin (NIH/OD) [E]" [REDACTED], "Baker, Rebecca (NIH/OD) [E]"

Cc: Anna Mazzucco [REDACTED]

Subject: Request: Source material for OD CJ Narrative draft

Dear all,

Thank you for all of your help in developing the OD Congressional Justification outline. Please see below a request for our next step.

ASK: Please submit any relevant source material on the subjects listed in the [OD CJ Outline](#) to the Teams folder named "[Narrative Source Material](#)" **by COB on Friday, September 4th**.

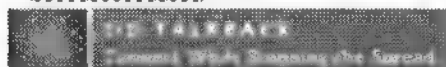
Background and Process: We greatly appreciate your help in developing the OD Congressional Justification outline for FY22. As the FY22 CJ Outline moves through the OLPA review process, we would like to begin collecting source material for the CJ Narrative to support the initial drafting process. IMOD will be taking the first pass at writing the Narrative section, the source material you contribute will be used to inform the writing process. For topics to submit source material on, please refer to the blue text in the CJ outline which indicates which OD Offices have played a role in each topic. Source material can include previously written or new reports, press releases, analyses, or any other documents which describe the program or topic. Once the Narrative is drafted, we will distribute it to you for your review before submission to OLPA.

For a reminder on the timeline for the OD CJ, please refer to the [Timeline](#) tab in Teams.

Please let us know if you have any questions or concerns. We appreciate you taking the time to provide feedback. Thank you in advance for your input!

Much appreciation,
Erica

Erica G. Landis, PhD
AAAS Science & Technology Policy Fellow
Immediate Office of the Director
National Institutes of Health
A: Building 1, Room 114
P: [REDACTED] b6



From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 2/28/2021 1:00:52 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Klock, Kevin (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6a4795309e54d3d887b0051aa88183b-klockka]
Subject: Re: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Terrific! Thank you Ashley. M.

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Saturday, February 27, 2021 at 7:51:53 PM
To: "Freire, Maria (FNIH) [T]" [b6]
Cc: "Hallett, Adrienne (NIH/OD) [E]" [b6], "Menetski, Joseph (FNIH) [T]" [b6], "Wholley, David (FNIH) [T]" [b6], "Klock, Kevin (FNIH) [T]" [b6]
Subject: Re: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Thanks, Maria. NCI reached out to Sara Selgrade at NIAID and it turns out they have been in contact with this company and provided POCs at the VRC along with other resources for preclinical testing. However, the company has to secure a vaccine developer to work with and it seems they may be having issues with this.

NIAID staff are working with NCI to provide the response and the best POC for follow up.

Thanks,
Ashley

On Feb 27, 2021, at 11:35 AM, Freire, Maria (FNIH) [T] [b6] wrote:

Adrienne, Ashley, just FYI and heads-up. Best, M.

From: "Menetski, Joseph (FNIH) [T]" [b6]
Date: Saturday, February 27, 2021 at 11:25:57 AM
To: "Lowy, Douglas (NIH/NCI) [E]" [b6], "Weingarten, Michael (NIH/NCI) [E]" [b6], "Gibbons, Holly (NIH/NCI) [E]" [b6], "Sharpless, Norman (NIH/NCI) [E]" [b6]
Cc: "Lubenow, Anne (NIH/NCI) [E]" [b6], "Johnson, Maureen (NIH/NCI) [E]" [b6], "Holohan, MK (NIH/NCI) [E]" [b6], "Freire, Maria (FNIH) [T]" [b6], "Wholley, David (FNIH) [T]" [b6]
Subject: RE: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Dear Doug,

Thank you for the note. Adding an immune activator to a vaccine to increase efficacy and immunogenicity sounds like an interesting approach. ACTIV has received one or two submissions to the asset portal with similar suggestions, but not using IL-12. As you probably know, ACTIV has not been focusing on this type of vaccine support, so in the past we have shared these submissions directly with the NIAID colleagues so they could assess the fit for their efforts.

Given that this has come through a member of congress, I would suggest having the company contact Dr. Ashley Parker in OD to ensure that this is addressed by the appropriate group in NIAID. Ashley and the NIAID group can assess how best to follow up with the potential vaccine approach.

Best regards,
Joe

From: Lowy, Douglas (NIH/NCI) [E] [b6]
Sent: Friday, February 26, 2021 5:43 PM
To: Weingarten, Michael (NIH/NCI) [E] [b6]; Gibbons, Holly (NIH/NCI) [E] [b6]; Sharpless, Norman (NIH/NCI) [E] [b6]
Cc: Lubenow, Anne (NIH/NCI) [E] [b6]; Johnson, Maureen (NIH/NCI) [E] [b6]; Holohan, MK (NIH/NCI) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: Re: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Holly and Ned,

To me, the next step for the company's proposed approach would be to evaluate it in an experimental model of infection/disease, preferably one for SARS-CoV-2. I'll write to Joe Menetski at FNIH, who is helping to coordinate the ACTIV preclinical working group, and see what he replies.

Thanks,
Doug

From: "Weingarten, Michael (NIH/NCI) [E]" [b6]
Date: Friday, February 26, 2021 at 2:57 PM
To: "Gibbons, Holly (NIH/NCI) [E]" [b6], "Sharpless, Norman (NIH/NCI) [E]" [b6], "Lowy, Douglas (NIH/NCI) [E]" [b6]
Cc: "Lubenow, Anne (NIH/NCI) [E]" [b6], Maureen Johnson [b6], "Holohan, MK (NIH/NCI) [E]" [b6]
Subject: RE: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Thanks Holly and Ned. We are taking a look at the description provided by the company and will follow up with you.

Michael

From: Gibbons, Holly (NIH/NCI) [E] [b6]
Sent: Friday, February 26, 2021 2:22 PM
To: Sharpless, Norman (NIH/NCI) [E] [b6]; Weingarten, Michael (NIH/NCI) [E] [b6]; Lowy, Douglas (NIH/NCI) [E] [b6]
Cc: Lubenow, Anne (NIH/NCI) [E] [b6]; Johnson, Maureen (NIH/NCI) [E]

[b6]; Holohan, MK (NIH/NCI) [E] [b6]
Subject: RE: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Thanks for your quick reply, Ned, and for adding Doug and Michael to the discussion.

Doug and Michael, we look forward to your input and will incorporate your guidance into our draft response. I just sent you both a copy of Rep. Cole's incoming letter, which includes a one-pager on Sonnet with more info about their work and this particular technology.

Best,
Holly

From: Sharpless, Norman (NIH/NCI) [E] [b6]
Sent: Friday, February 26, 2021 2:15 PM
To: Gibbons, Holly (NIH/NCI) [E] [b6]
Cc: Lubenow, Anne (NIH/NCI) [E] [b6]; Johnson, Maureen (NIH/NCI) [E]
[b6]; Holohan, MK (NIH/NCI) [E] [b6]; Lowy, Douglas
(NIH/NCI) [E] [b6]; Weingarten, Michael (NIH/NCI) [E] [b6]
Subject: RE: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

This is not dissimilar from the Oncoimmune story (which was one of our SBIR companies), which started as cancer drug but found utility in COVID
<https://www.fiercebiotech.com/biotech/merck-inks-425m-oncoimmune-buyout-to-bag-covid-19-drug>

I don't know what stage Sonnet is at, but it might be appropriate for them to work with the NCI SBIR program for their cancer work. I am cc'ing Michael in case he can figure out more about the company and see if they would be a good fit.

As for the vaccine work, I think they would be better served by contacting NIAID. I am not sure if it would be better for them to contact NIAID SBIR program or the Vaccine Branch. Perhaps Doug or Michael will have thoughts on that as well

Ned

From: Gibbons, Holly (NIH/NCI) [E] [b6]
Sent: Friday, February 26, 2021 10:30 AM
To: Sharpless, Norman (NIH/NCI) [E] [b6]
Cc: Lubenow, Anne (NIH/NCI) [E] [b6]; Johnson, Maureen (NIH/NCI) [E]
[b6]; Holohan, MK (NIH/NCI) [E] [b6]
Subject: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Dear Dr. Sharpless,

Congressman Tom Cole (R-OK) is reaching out to seek your advice. I am attaching a letter we received this week through the NIH correspondence system.

He is seeking advice to share with a New Jersey-based biotech, Sonnet BioTherapeutics. The company is looking to use an agent that has shown to enhance immune response in the context of cancer immunotherapy (Interleukin-12 delivered through Sonnet's binding platform, more info in the attachment), and combine it with a COVID-19 vaccine in a clinical trial to evaluate the potential to enhance immune response.

We understand there may not be a relevant opportunity at NCI for this company, however this is a good opportunity to provide Rep. Cole with a helpful response. He is asking if it would be possible to connect the company directly with you – if you prefer to provide suggestions to connect the company with other relevant colleagues, whether at NCI, NIAID, or elsewhere in the field, we can also focus the response in that direction.

Our written response can be brief, and is **due back to NIH Exec Sec by Wednesday, 3/3 COB**. We welcome your thoughts re: guidance to provide to Rep. Cole, and based on your input we will develop a formal written response for your signature.

Best,
Holly

Holly Aprea Gibbons, MPP
Deputy Director, Office of Government and Congressional Relations
National Cancer Institute

Direct: [REDACTED] b6

Mobile: [REDACTED] b6

[REDACTED] b6

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 7/22/2020 2:29:07 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: Re: Virtual Congressional Briefing on Human Challenge Trials

Maybe Congress needs to call upon some bioethicists. M.

On Jul 21, 2020, at 10:23 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

From: Mascola, John (NIH/VRC) [E] [b6]
Sent: Tuesday, July 21, 2020 8:46 PM
To: Lowy, Douglas (NIH/NCI) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]
Cc: Hallett, Adrienne (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]
Subject: RE: Virtual Congressional Briefing on Human Challenge Trials

I agree with Doug. At very least, we need and effective therapy. And we may have vaccine signal before CHIM could be done.

Regarding Adrian Hill, I don't know of current direct interactions with him or Oxford, on CHIM – and there are issues there that may be better expressed verbally. NIAID/DMID has plans to develop a challenge stock – so have copied Emily Erbeling here.

John

From: Lowy, Douglas (NIH/NCI) [E] [b6]
Sent: Tuesday, July 21, 2020 1:42 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Mascola, John (NIH/VRC) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]
Cc: Hallett, Adrienne (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]

b6

; Wolinetz, Carrie (NIH/OD) [E]

b6

Burklow, John (NIH/OD) [E]

Subject: Re: Virtual Congressional Briefing on Human Challenge Trials

Hi Francis,

To me, there is an important ethical question. Do people have a right to risk their lives in this way by taking a challenge virus for which – if they developed serious illness – there is not yet an agreed upon highly effective rescue drug? Even with a strongly worded informed consent, would a DSMB approve such a trial? A related issue is what the public response might be, and its potential impact on subsequent vaccine acceptance, if one or more participants in a challenge trial had an adverse outcome, regardless of whether they were in the control or vaccinated group.

Doug

From: "Collins, Francis (NIH/OD) [E]"

b6

Date: Tuesday, July 21, 2020 at 1:17 PM

To: "Mascola, John (NIH/VRC) [E]"

b6

"Fauci, Anthony (NIH/NIAID) [E]"

b6

"Lowy, Douglas (NIH/NCI) [E]"

b6

Cc: "Hallett, Adrienne (NIH/OD) [E]"

b6

"Tabak, Lawrence (NIH/OD) [E]"

b6

"Wolinetz, Carrie (NIH/OD) [E]"

b6

(NIH/OD) [E]"

b6

Subject: FW: Virtual Congressional Briefing on Human Challenge Trials

Hi John, Doug, and Tony,

See below, including the hot links to Oxford Jenner Institute and statements from Adrian Hill that he intends to conduct a human challenge trial by the end of the year, regardless of the results of the current field trials. I would have thought the NEJM paper on the logistical challenges of CHIM would have slowed down the momentum for the challenge trial idea, but the organization 1Day Sooner has not seemed to take notice – and has captured the altruistic spirit of a lot of volunteers. Now it seems they've attracted the interest of the Congress also.

Do we (NIH or ACTIV) have any direct interactions with Adrian Hill, or with 1Day Sooner? Might this be a good moment to get reasonable people together?

Francis

From: Hallett, Adrienne (NIH/OD) [E]

b6

Sent: Tuesday, July 21, 2020 11:58 AM

To: Collins, Francis (NIH/OD) [E]

b6

; Tabak, Lawrence (NIH/OD) [E]

b6

Wolinetz, Carrie (NIH/OD) [E]

b6

Subject: FW: Virtual Congressional Briefing on Human Challenge Trials

FYI. I've gotten a few of these....

From: Natasha Dolmon

b6

Sent: Tuesday, July 21, 2020 11:30 AM

Subject: Virtual Congressional Briefing on Human Challenge Trials

Good morning ,

APAR0000000453

My name is Natasha Dolmon - the Legislative Director for 1Day Sooner. Thank you for speaking with us on June 15th about human challenge trials, and how they may hasten the development of a coronavirus vaccine. Challenge trials have been brought to the forefront - We recently partnered with Oxford's Jenner Institute in the production of a challenge virus, a necessary precondition for challenge trials, after they announced their intention to run challenge trials this year. Additionally, this preprint polling data indicates there is public support for the use of challenge trials.

We are offering a venue to discuss challenge trials, in the hope that you return to Rep. Sherman with new information. We're planning on hosting a virtual congressional briefing on July 28th at 2:00 pm. Our team is finalizing a group of panelists composed of signatories to our recent NIH open letter, who can offer their perspectives on the vaccine development process. We're expecting Rep. Bill Foster of Illinois to present opening remarks.

Would you two, or another colleague, be available to spectate? If so, I will forward you our invitation from Microsoft Teams, where you can either view the live video directly or attend via the web (no sign-in required). You would be welcome to submit questions ahead of time. Any questions I can help answer?

Best,

Natasha Dolmon
Advocacy and Outreach
1Day Sooner

From: Meltzer, Abbey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C341D86CF7404A78AC8F852E698E5382-MELTZERAK]
Sent: 4/29/2020 10:34:32 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Hill inquiry re: ACTIV

You're welcome.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, April 29, 2020 5:59 PM
To: Meltzer, Abbey (FNIH) [T] [b6]
Subject: RE: Hill inquiry re: ACTIV

Hi Abbey,

Thank you very much for sharing this information.

Ashley

From: Meltzer, Abbey (FNIH) [T] [b6]
Sent: Wednesday, April 29, 2020 5:50 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Hill inquiry re: ACTIV

Hi Ashley,

I wanted to give you a heads up that Joe Banez, a health aide for the majority at the House, Energy and Commerce Committee reached out to my colleague Kevin Klock in relation to ACTIV. He asked where to send inquiries for those who may want to participate in ACTIV, and we responded that NIH was collecting that information but should he have a question about this process to reach out to you, as you are our contact for sharing these requests at this time.

Best,
Abbey

Abbey Meltzer
Vice President of Communications and Events
Foundation for the National Institutes of Health
[b6] fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Berkson, Laura (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ADB561AB47E54FDC94E2A54682514434-BERKSONLD]
Sent: 4/29/2020 10:21:26 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Hill inquiry re: ACTIV

Great – thanks, Ashley!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, April 29, 2020 6:14 PM
To: Berkson, Laura (NIH/OD) [E] [b6]
Subject: RE: Hill inquiry re: ACTIV

Hi Laura,

I will absolutely send Joe your way and follow up with you if I hear anything.

There has been a combination of efforts to capture interested companies for ACTIV. FNIH usually sends the request they receive directly to me as I am triaging the request for Dr. Collins and we share these with the ACTIV working groups. I also upload them into DDRMS to ensure they receive a standard response from ES until we have the ACTIV portal up and running. In some cases FNIH will follow up with companies directly and meet with them when appropriate.

I think it's fine to keep the process as you've outlined below – these will be routed to us in any case.

Thanks,
Ashley

From: Berkson, Laura (NIH/OD) [E] [b6]
Sent: Wednesday, April 29, 2020 6:05 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Hill inquiry re: ACTIV

Hi Ashley,

Thanks for flagging! Could you please let me know if you hear from Joe about this? I talk to him a few times a week so if there is anything I should pass on please let me know.

Also, I wanted to flag that I had an Energy and Commerce minority staffer ask a similar question. I was told to tell her: "companies should reach out to Joe Menetski, AVP of Research Partnerships at the Foundation [b6] with copy to David Wholley, SVP of Research Partnerships at [b6]"

Moving forward, are you a more appropriate POC?

Laura

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, April 29, 2020 5:59 PM
To: Meltzer, Abbey (FNIH) [T] [b6]
Subject: RE: Hill inquiry re: ACTIV

Hi Abbey,

Thank you very much for sharing this information.

Ashley

From: Meltzer, Abbey (FNIH) [T] [b6]

Sent: Wednesday, April 29, 2020 5:50 PM

To: Parker, Ashley (NIH/OD) [E] [b6]

Subject: Hill inquiry re: ACTIV

Hi Ashley,

I wanted to give you a heads up that Joe Banez, a health aide for the majority at the House, Energy and Commerce Committee reached out to my colleague Kevin Klock in relation to ACTIV. He asked where to send inquiries for those who may want to participate in ACTIV, and we responded that NIH was collecting that information but should he have a question about this process to reach out to you, as you are our contact for sharing these requests at this time.

Best,
Abbey

Abbey Meltzer

Vice President of Communications and Events

Foundation for the National Institutes of Health

[b6] fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 12/30/2020 10:43:04 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: inquiry on fluvoxamine- for response 1/5

Hi David,

Thanks so much for the information and for the quick response!

Happy New Year!

Thanks,

Lauren

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, December 30, 2020 5:16 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: RE: inquiry on fluvoxamine- for response 1/5

Hi Lauren –

The situation is that the ACTIV agent prioritization team looked at fluvoxamine and was actually initially supportive of testing it, but Dr. Lenz said he had started his own Phase 3 trial in hand (n~800 patients), so ACTIV did not proceed with what would have been a duplicative effort. That said, the ACTIV team left the door open to take on Dr. Lenz's trial if there are recruitment issues. Meanwhile Dr. Lenz has made a grant request for more financial support for his trial to NIH which I believe is due to be considered by NIAID in January, and we have been exploring (as of Dec. 21) with the ACTIV trial teams ways in which they could help Dr. Lenz boost enrollment in the interim. We are keeping NIH leadership in the loop on this. Thanks, David

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Wednesday, December 30, 2020 3:31 PM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]
Subject: inquiry on fluvoxamine- for response 1/5

Hi Stacey,

We just received an inquiry on fluvoxamine, which will be used for a response to a question from a Congressional Representative. We asked about the turnaround time, and they are hoping for early next week (Monday/Tuesday), so this is not something you need to respond today, but wanted to pass along so you have it (sorry to be sending today if you are still on vacation).

From my understanding, as of October, FNIH/ACTIV had been in contact with Dr. Lenz (PI on a fluvoxamine study) a number of times, including to request further information that ACTIV reviewers have requested on the agent, and ACTIV was in the process of reviewing the compound to evaluate whether or not to include the agent in an ACTIV trial.

The Congressman's staff is asking for information on Fluvoxamine trials. Do you have any updates on this agent? If you could provide any information you might have early next week, it would be much appreciated!

Thanks so much, and Happy New Year!

Lauren

Lauren Brodd, Ph.D.
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health

b6



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OSP Blog: [Under the Poliscopes](#)

Twitter: @CWolinetzNIH

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/18/2020 10:47:42 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200918_v2.pptx - please use this version
Attachments: ACTIV Daily Update 20200918_v2.pptx

Apologies, just received a late breaking addition to the slides. Please use these for our war room discussions this morning, Friday September 18.

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 9/16/2020 3:26:28 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: RE: Follow up from this morning's discussion about ACTIV-1 contract difficulties with Janssen

Thanks David. This is very helpful information. I told Lili Portilla (our TT person) about Wade after our call this morning and it turns out she had already reached out to him on this and that he was being very helpful in resolving the situation. And thanks for the info about Ruxandra - I hadn't realized she is on the CT WG. Rux and I are close friends from her years at the EC. I will reach out to Rux if we don't make prompt headway. Thanks, Chris

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, September 16, 2020 10:06 AM
To: Austin, Christopher (NIH/NCATS) [E] [b6]
Cc: Lane, Cliff (NIH/NIAID) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: Follow up from this morning's discussion about ACTIV-1 contract difficulties with Janssen

Hi Chris –

I did check around and as I suspected while FNIH has done a ton of partnerships with Janssen, none of them have been clinical trials (they did not participate in ISPY and have yet to be involved in LungMAP). Wade Green is probably the best person to speak to as Cliff suggested—one would hope he is at least knowledgeable about who worked on the ACTT CTA. Stacey Adam also has established a pretty good relationship with Ruxandra Draghili who is Janssen's rep to the Clinical Trial WG, and has offered to have a back channel conversation with her about whom at Janssen legal might be worth a call—but we will do that only if and when you formally say it is OK with you. Let me know.

Thanks, David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 9/14/2020 6:34:54 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: FW: More competition for ACTIV -1
Attachments: ITAC_Protocol V 1.0.pdf

From the PI of the ACTIV-1 trial...an example of what all the trials are dealing with, and why coordination of the sort the trans-trial group is doing is so important.

From: Powderly, Bill [b6]
Sent: Monday, September 14, 2020 12:43 PM
To: Bozzette, Sam (NIH/NCATS) [E] [b6]
Cc: Atkinson, Jane (NIH/NCATS) [E] [b6] Boucher, Cynthia (NIH/NCATS) [E]
[b6]
Subject: More competition for ACTIV -1

NIAID has just sent this to sites - another study for acutely ill hospitalized patients - being run by Insight- same team as ACTIV-3. Not for ICU patients but would overlap with ACTIV 1 and 3.

We are going to say No but it is a challenge when NIH is cannibalizing itself at the sites.

William G. Powderly MD
J. William Campbell Professor of Medicine
Larry J. Shapiro Director, Institute for Public Health
Director, Institute of Clinical and Translational Sciences
Co-Director, Division of Infectious Diseases
Washington University in St. Louis

Assistant: Stephanie Montgomery
Phone: [b6]
Fax 314-454-8687
[b6]

BECAUSE

we are in this together



Practice Personal
Hygiene



Wear a mask



Practice Physical
Distancing

Institute for Public Health at Washington University in St. Louis

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/16/2020 11:09:55 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: 9.15.2020 Needs Assessment Meeting_v1.pdf
Attachments: 9.15.2020 Needs Assessment Meeting_v1.pdf

Here are slides from yesterday's Needs Assessment summary meeting. I will not go through this page by page—will instead summarize outcomes and action items—but thought you might appreciate having the slides. David

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/16/2020 10:54:25 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200916 ver2.pptx--Please use this version
Attachments: ACTIV Daily Update 20200916 ver2.pptx

Begging your pardon, I just received a new version of the war room slides for this morning, Wednesday September 16, containing an additional update from the Clinical Trials WG. Please use this version for our discussions today. Thanks, David

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/16/2020 10:36:54 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200916.pptx
Attachments: ACTIV Daily Update 20200916.pptx

Slide for this morning's war room call, Wednesday September 16.

From: Douek, Daniel (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE1D10C433884C408AF670E21F0D2D66-DDOUEK]
Sent: 9/6/2020 3:23:34 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
Subject: Re: Article on COVID and DOE analysis

Thanks Francis, Aviv's analysis makes a lot of sense.

I will touch base with Tim Schacker to see if the U. Minn Losartan trial has produced any interesting clinical outcome data.

danny

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Sunday, September 6, 2020 at 10:30 AM
To: John Mascola [b6] "Lane, Cliff (NIH/NIAID) [E]" [b6], Daniel Douek [b6]
Cc: "Fauci, Anthony (NIH/NIAID) [E]" [b6] "Tabak, Lawrence (NIH/OD) [E]" [b6] "Wholley, David (FNIH) [T]" [b6], "Adam, Stacey (FNIH) [T]" [b6] "Parker, Ashley (NIH/OD) [E]" [b6] "Read, Sarah (NIH/NIAID) [E]" [b6]
Subject: RE: Article on COVID and DOE analysis

Hi John, Cliff, and Danny,

At my request, Aviv Regev (now at Genentech) has looked at the scRNA-seq data that compares LUL lung between normal and COVID-19. Her analysis of the expression data is attached. The claims of dramatic differences in gene expression from those 8 BAL samples don't seem to hold up very well. She promises to send more results today about other organs.

Francis

Dear Francis,

We looked at the paper, and tried to quickly pull the key genes they claim may be impacted.

The results for lung are in the attached slide, each comparing COVID lung (autopsies) to healthy lung (declined organ donation source). We are still doing some sanity checks, so these should be considered preliminary.

Tomorrow, we expect to share kidney, liver and heart data.

While some of the assertions are somewhat supported, we do not see support for others. The DEG coefficients mentioned in that paper are so high, it gives us some pause. I do know the last author (Bruce Arronow) well, if you'd like me to ask him more questions; for now, we just went with the genes in the paper.

Thanks!

Aviv

PS we expect to release this data resource (along with another one from an effort in NYC) for querying in the next few days, even before writing and submitting the paper. We hope this will help others with various queries.

From: Mascola, John (NIH/VRC) [E] [b6]
Sent: Saturday, September 5, 2020 9:54 PM
To: Lane, Cliff (NIH/NIAID) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E]
[b6]; Read, Sarah (NIH/NIAID) [E] [b6]
Subject: RE: Article on COVID and DOE analysis

I asked Danny Douek at VRC for his thoughts: They are below.

I'm familiar with this paper (published 2 months ago). An extraordinary amount of speculation based on RNAseq data in 8 people. They may have a point about what happens in ARDS but It may not be specific only to COVID. I think the ACE2 angle is likely coincidence.

Either way, I think the best way to address the specific question is to contact Tim Schacker at U Minn. They have a trial ongoing of Losartan (an ARB inhibitor) in COVID-19. We are receiving samples at VRC. The aim is specifically to interfere with the RAS and thus address the "bradykinin theory".

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Saturday, September 5, 2020 8:56 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]; Mascola, John (NIH/VRC) [E] [b6];
Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Adam,
Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Read, Sarah (NIH/NIAID) [E]
[b6]
Subject: Re: Article on COVID and DOE analysis

My initial impression aligns with the comment below from the article:

" The bradykinin hypothesis provides a model that "contributes to a better understanding of Covid-19" and "adds novelty to the existing literature," according to scientists Frank van de Veerdonk, Jos WM van der Meer, and Roger Little, who peer-reviewed the team's paper."

I think there is fairly universal agreement that excessive inflammation is a major contributor to severe disease. Of note, steroids (such as dexamethasone) have some effects on bradykinin but may not be the most potent approach.

Interestingly, fresh frozen plasma has been used in some instances of ACE-inhibitor induced angioedema with anecdotal reports of success.

In response to an earlier email in follow up of the discussion with Dr. Birx, Sarah Read (copied) noted:

"Icatibant was also on the short list for ACTT3. Notes from John Beigel say "Potential role for bradykinin in CoV pathogenesis. Insufficient data in SARS-CoV-2 for a large study."

Bottom line from me - may be worth a closer look; perhaps via ACTIV team 2 as an initial step.

Cliff

On Sep 5, 2020, at 5:44 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi Tony, Cliff, and John,

See query below from the Secretary. The published article referred to is [h](#)

What do you think of this bradykinin theory, based on systems biology analysis of gene expression in BAL cells? It would seem straightforward to assay tissues to see if the postulated elevations are really present.

I think I know now why Deb Birx was asking if any of the ACTIV prioritized therapeutics were bradykinin inhibitors.

I'll also query Aviv Regev (co-lead of the Human Cell Atlas) to see what she would say about this.

Francis

From: [b6] (OS/IOS) [b6]
Sent: Saturday, September 5, 2020 5:28 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Redfield, Robert R. (CDC/OD) [b6]
Cc: Mango, Paul (HHS/IOS) [b6]
Subject: Article on COVID and DOE analysis

Would love your thoughts on this. Orally is preferable.

<https://elemental.medium.com/a-supercomputer-analyzed-covid-19-and-an-interesting-new-theory-has-emerged-31cb8eba9d63>

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 9/6/2020 3:09:10 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponeIm]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Thanks!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, September 4, 2020 5:13 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Francis,

With many thanks to Lauren and Jill, attached is the revised grid with "coming soon" listed for those agents that should not be made public yet i.e. trials that have not yet launched. We will continue to update the grid as the trials launch but I wanted to share with you again before sharing broadly with the war room and ACTIV Tx WG who've asked to review.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 3:03 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Next week is fine.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 2:57 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Yes, we can do this. How soon would you need it?

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 2:28 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

This is looking good. Thinking about a way to make this of wider use without disclosing confidential information, is there a version of this grid that could have the hot links provided for trials that have already been publicly announced, but a "coming soon" link for the others?

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 2:23 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Francis, David, and Maria,

With many thanks to Jill, attached is a PDF version of the CT grid without the links to the confidential agents etc.

I hear the Clinical Tx WG is interested in reviewing and providing edits/additions. If the ACTIV-4/NHLBI reps on the WG would like to make changes they should work closely with Amy Patterson – the current info provided was vetted by Amy and her team.

Once the WG group has collective edits we will update those on the live version. Please let us know if this plan works for FNIH—cc'ing Stacey as well.

Thanks,
Ashley

From: Anderson, James (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]
Sent: 9/10/2020 6:51:23 PM
To: Hall, Matthew (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c76a7b2623714aaaa095fda97973f5e6-hallma_b4f6]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Davis, Mindy (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868464dab61f45898ccf4d4c6b44523a-davism12]; Dieffenbach, Carl (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94acc37973d346fa98dfe16cd1bf7013-cdieffenba]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Auchincloss, Hugh (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9304c753bb9e422c977dddab54da924b-auchincloss]
Subject: RE: Follow-up on antiviral targets

Matt,
I will send you the planning documents for the nAb Summit. We used a fairly directive approach with the participants and it worked on a tight timeline. The final 508 compliant report should go on the NIH website today. Happy to help or advise or spectate.
Jim

From: Hall, Matthew (NIH/NCATS) [E] [b6]
Sent: Thursday, September 10, 2020 12:59 PM
To: Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Davis, Mindy (NIH/NIAID) [E] [b6]; Dieffenbach, Carl (NIH/NIAID) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]; Marston, Hilary (NIH/NIAID) [E] [b6]; Auchincloss, Hugh (NIH/NIAID) [E] [b6]
Subject: Re: Follow-up on antiviral targets

Thanks Cliff,

We would be happy to work with you on evolving this concept. Happily, Mindy Davis had received approval to join our tentative organizing group to help plan a meeting along the lines Chris mentioned below. We'll hit pause and I'll get together with Mindy to discuss potential scope and format, and perhaps we can we can

identify whether one or more meetings are needed. We can build out the organization from there. If you are able join for a conversation to share your thoughts that would be greatly appreciated – as always, all are welcome. We envisaged that this would a virtual meeting, and of high interest to the broader translational science and biomedical communities, with appropriate NIH leadership involved.

The HEAL Symposium 2-day meeting initiated in a similar way under our Assay Guidance Manual banner, but the concept grew and it was organized by a group from NCATS, NINDS, NIDA, NCCIH.

Thanks,
Matt

Matthew D. Hall
Acting Director, Early Translation Branch
Group Leader, Biology

National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health
9800 Medical Center Drive
Rockville, MD 20850
Office [b6]
<https://ncats.nih.gov/staff/hallma>

@cispt2

NCATS Website: <http://ncats.nih.gov>

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: "Lane, Cliff (NIH/NIAID) [E]" [b6]
Date: Thursday, September 10, 2020 at 11:45 AM
To: "Austin, Christopher (NIH/NCATS) [E]" [b6]
Cc: Matthew Hall [b6], "Wholley, David (FNIH) [T]" [b6], "Collins, Francis (NIH/OD) [E]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Freire, Maria (FNIH) [T]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], "Davis, Mindy (NIH/NIAID) [E]" [b6], "Dieffenbach, Carl (NIH/NIAID) [E]" [b6], "Erbelding, Emily (NIH/NIAID) [E]" [b6], "Marston, Hilary (NIH/NIAID) [E]" [b6], "Auchincloss, Hugh (NIH/NIAID) [E]" [b6]
Subject: Follow-up on antiviral targets

Chris,

There is currently nothing of this type being planned within NIAID. We would be happy to work with you and the others to do something in this area. Mindy Davis (copied) will be our point of contact. From my perspective something like the mAB workshop might work well but I do not have a strong opinion. If we take that approach I might do one on viral targets other than spike protein and the other on host targets. I have copied Hugh, Emily, Carl and Hilary to keep them in the loop.

Cliff

From: "Austin, Christopher (NIH/NCATS) [E]" [b6]
Date: Thursday, September 10, 2020 at 10:09 AM
To: "Lane, Cliff (NIH/NIAID) [E]" [b6]

Cc: "Hall, Matthew (NIH/NCATS) [E]" [b6]

Subject: Potential COVID targets for DD workshop

Hi Cliff,

In follow up of our conversation about this on the war room yesterday, I'm connecting you with Matt Hall, who is the NCATS lead on the potential COVID targets workshop we've been considering. We've envisioned this as a COVID version of the HEAL (opioid) targets meeting co-run by NCATS, NIDA, and NINDS a few years

back: <https://ncats.nih.gov/pubs/features/heal-symposium>. Another model would be the COVID mAb workshop FNIH ran. Given that Tony promised D Birx he would see that a workshop happened, I don't want to step on toes. How do you suggest we move forward on a symposium perhaps co-run by NIAID, NCATS, and FNIH?

Chris

From: Lane, Cliff (NIH/NIAID) [E] [b6]

Sent: Friday, September 4, 2020 3:46 PM

To: Austin, Christopher (NIH/NCATS) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]

Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]

Subject: Re: Call with Dr. Birx

The way we left the call was that Tony would take responsibility for a follow-up. I think if there is something being planned for the near future that would cover it.

Cliff

From: "Austin, Christopher (NIH/NCATS) [E]" [b6]

Date: Friday, September 4, 2020 at 3:43 PM

To: "Lane, Cliff (NIH/NIAID) [E]" [b6]; "Wholley, David (FNIH) [T]" [b6]; "Collins, Francis (NIH/OD) [E]" [b6]; Lawrence Tabak <[b6]> "Freire, Maria (FNIH) [T]" [b6]; "Parker, Ashley (NIH/OD) [E]" [b6]; "Anderson, James (NIH/OD) [E]" [b6]

Cc: Anthony Fauci <[b6]>

Subject: RE: Call with Dr. Birx

Hi Cliff,

We at NCATS and our Trans-NIH 8 group colleagues (that we run w NIAID) just today began discussions on the concept of a COVID Therapeutic Discovery Symposium – 2 day meeting similar to the one we did with NIDA and NINDS on HEAL. We would be enthusiastic about helping with the Birx concept and having our efforts merged with those. What was the action item from the Birx call re the symposium? Was someone tasked with making that happen?

Best

Chris

From: Lane, Cliff (NIH/NIAID) [E] [b6]

Sent: Friday, September 4, 2020 2:15 PM

To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher

(NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]
Subject: Call with Dr. Birx

ACTIV War Room colleagues,

Tony (copied), Janet, myself and several other just finished a call with Dr. Birx focused on the current state of therapeutics. One action item out of that call was to convene a "workshop" on targeted drug discover for SARS-CoV-2 similar to what had been done in the past for HIV (polymerase; protease, etc.). It would seem like this might be a good task for ACTIV Team 1 and Tony (copied) asked that I send this note. An alternative would be to do a workshop such as was recently done for the MoAb.

Dr. Birx also had a specific request as to whether or not ACTIV has vetted inhibitors of the bradykinin pathway and I sent a note to Sarah Read with this question.

Thanks,

Cliff

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/14/2020 11:29:11 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; John H. Freeman [b6] Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: 9.11.2020 Needs Assessment Meeting_FINAL.pdf
Attachments: 9.11.2020 Needs Assessment Meeting_FINAL.pdf

Slides from the first Needs Assessment Survey results discussion last Friday, 9/11.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/14/2020 11:20:10 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200914.pptx
Attachments: ACTIV Daily Update 20200914.pptx

Slides for this morning's war room, Monday September 14.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/4/2020 11:14:51 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200904.pptx
Attachments: ACTIV Daily Update 20200904.pptx

For this morning's war room, Friday September 4.

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 8/29/2020 6:27:30 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links
Attachments: DRAFT NIH_ACTIV Checkerboard_8.29.2020.pptx; Checkerboard for ACTIV and NIH COVID Trials 08.29.2020.xlsx; Copy of Planned COVID-19 clinical studies master_2020.08.11_AP0813_LB0829.xlsx

Flag: Follow up

Hi Ashley,

Attached are updated versions of the grid, CT info, and master NIH trials:

b5

Hope that all makes sense. Let me know if you have any questions.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 3:43 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: NIH and ACTIV Clinical Trial Grid w/o Links

APAR0000000677

Hi Lauren,

Dr. Collins has asked if we could make a version with "coming soon" for those trials that are not yet public. Would you be able to assist with changing the links of the agents to say "coming soon" for those trials which do not yet have a CT.gov number? Each trial with a T inside a white triangle is not yet public unless you've found updates.

I know you are working on updating the current spreadsheet with ACTIV CT information. For your reference and additions, I am also attaching the spreadsheet with the NIH ongoing and planned trials that are shaded blue on the current grid (highlighted yellow on the spreadsheet). We will need to include these in the NIH tab of the spreadsheet you are updating and look to see if CT.gov numbers are available yet. Some of these NIH trials have been funded but others were not at the time the ICs provided the spreadsheet – QVR is a good tool for checking the status if needed to confirm.

Happy to chat via phone if needed.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 2:28 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6] Freire, Maria (FNIH) [T] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

This is looking good. Thinking about a way to make this of wider use without disclosing confidential information, is there a version of this grid that could have the hot links provided for trials that have already been publicly announced, but a "coming soon" link for the others?

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 2:23 PM
To: Collins, Francis (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] <dwholley@fnih.org>; Freire, Maria (FNIH) [T] [b6]
Cc: George, Jill (NIH/OD) [E] [b6] Adam, Stacey (FNIH) [T] [b6]
Subject: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Francis, David, and Maria,

With many thanks to Jill, attached is a PDF version of the CT grid without the links to the confidential agents etc.

I hear the Clinical Tx WG is interested in reviewing and providing edits/additions. If the ACTIV-4/NHLBI reps on the WG would like to make changes they should work closely with Amy Patterson – the current info provided was vetted by Amy and her team.

Once the WG group has collective edits we will update those on the live version. Please let us know if this plan works for FNIH—cc'ing Stacey as well.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/11/2020 11:15:41 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200911.pptx
Attachments: ACTIV Daily Update 20200911.pptx

Here are slides for this morning's war room, Friday September 11, 2020

From: Anderson, James (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]
Sent: 9/4/2020 7:54:01 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]
Subject: RE: Call with Dr. Birx

We could also repeat the successful nAb Summit format. Let us know.

The full draft report and meeting summary was finished today and will be on an NIH website when Francis approves.

Jim

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Friday, September 4, 2020 3:49 PM
To: Lane, Cliff (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]
Subject: RE: Call with Dr. Birx

Very good just let us know if/how we could help. Chris

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Friday, September 4, 2020 2:46 PM
To: Austin, Christopher (NIH/NCATS) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]
Subject: Re: Call with Dr. Birx

The way we left the call was that Tony would take responsibility for a follow-up. I think if there is something being planned for the near future that would cover it.

Cliff

From: "Austin, Christopher (NIH/NCATS) [E]" [b6]
Date: Friday, September 4, 2020 at 3:43 PM
To: "Lane, Cliff (NIH/NIAID) [E]" [b6], "Wholley, David (FNIH) [T]" [b6],
"Collins, Francis (NIH/OD) [E]" [b6], Lawrence Tabak [b6], "Freire,
Maria (FNIH) [T]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Anderson,
James (NIH/OD) [E]" [b6]
Cc: Anthony Fauci [b6]
Subject: RE: Call with Dr. Birx

Hi Cliff,

We at NCATS and our Trans-NIH 8 group colleagues (that we run w NIAID) just today began discussions on the concept of a COVID Therapeutic Discovery Symposium – 2 day meeting similar to the one we did with NIDA and NINDS on HEAL. We would be enthusiastic about helping with the Birx concept and having our efforts merged with those. What was the action item from the Birx call re the symposium? Was someone tasked with making that happen?

Best

Chris

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Friday, September 4, 2020 2:15 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak,
Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher
(NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James
(NIH/OD) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]
Subject: Call with Dr. Birx

ACTIV War Room colleagues,

Tony (copied), Janet, myself and several other just finished a call with Dr. Birx focused on the current state of therapeutics. One action item out of that call was to convene a "workshop" on targeted drug discover for SARS-CoV-2 similar to what had been done in the past for HIV (polymerase; protease, etc.). It would seem like this might be a good task for ACTIV Team 1 and Tony (copied) asked that I send this note. An alternative would be to do a workshop such as was recently done for the MoAb.

Dr. Birx also had a specific request as to whether or not ACTIV has vetted inhibitors of the bradykinin pathway and I sent a note to Sarah Read with this question.

Thanks,

Cliff

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/28/2020 10:42:34 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200828.pptx
Attachments: ACTIV Daily Update 20200828.pptx

Attached are the slides for this morning's war room, Friday August 28.

BTW I have a hard stop at 8:30
David

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 9/10/2020 4:19:16 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Hall, Matthew (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c76a7b2623714aaaa095fda97973f5e6-hallma_b4f6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Davis, Mindy (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868464dab61f45898ccf4d4c6b44523a-davism12]; Dieffenbach, Carl (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94acc37973d346fa98dfe16cd1bf7013-cdieffenba]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Auchincloss, Hugh (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9304c753bb9e422c977dddab54da924b-auchincloss]
Subject: RE: Follow-up on antiviral targets

Happy to have Jim take this on if he is willing

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Thursday, September 10, 2020 12:03 PM
To: Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Cc: Hall, Matthew (NIH/NCATS) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Davis, Mindy (NIH/NIAID) [E] [b6]; Dieffenbach, Carl (NIH/NIAID) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]; Marston, Hilary (NIH/NIAID) [E] [b6]; Auchincloss, Hugh (NIH/NIAID) [E] [b6]
Subject: Re: Follow-up on antiviral targets

Yes it was.

From: "Freire, Maria (FNIH) [T]" [b6]
Date: Thursday, September 10, 2020 at 12:01 PM
To: "Lane, Cliff (NIH/NIAID) [E]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6]
Cc: "Hall, Matthew (NIH/NCATS) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], Francis Collins [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Anderson, James

(NIH/OD) [E]" [b6], "Davis, Mindy (NIH/NIAID) [E]" [b6],
"Dieffenbach, Carl (NIH/NIAID) [E]" [b6], "Erbelding, Emily (NIH/NIAID) [E]"
[b6], "Marston, Hilary (NIH/NIAID) [E]" [b6], "Auchincloss, Hugh
(NIH/NIAID) [E]" [b6]

Subject: Re: Follow-up on antiviral targets

I believe the very successful mAB meeting that is mentioned below was run by Jim's folks in conjunction with Janet's team. M.

From: "Lane, Cliff (NIH/NIAID) [E]" [b6]
Date: Thursday, September 10, 2020 at 11:45:26 AM
To: "Austin, Christopher (NIH/NCATS) [E]" [b6]
Cc: "Hall, Matthew (NIH/NCATS) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Collins, Francis (NIH/OD) [E]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Freire, Maria (FNIH) [T]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], "Davis, Mindy (NIH/NIAID) [E]" [b6], "Dieffenbach, Carl (NIH/NIAID) [E]" [b6], "Erbelding, Emily (NIH/NIAID) [E]" [b6], "Marston, Hilary (NIH/NIAID) [E]" [b6], "Auchincloss, Hugh (NIH/NIAID) [E]" [b6]
Subject: Follow-up on antiviral targets

Chris,

There is currently nothing of this type being planned within NIAID. We would be happy to work with you and the others to do something in this area. Mindy Davis (copied) will be our point of contact. From my perspective something like the mAB workshop might work well but I do not have a strong opinion. If we take that approach I might do one on viral targets other than spike protein and the other on host targets. I have copied Hugh, Emily, Carl and Hilary to keep them in the loop.

Cliff

From: "Austin, Christopher (NIH/NCATS) [E]" [b6]
Date: Thursday, September 10, 2020 at 10:09 AM
To: "Lane, Cliff (NIH/NIAID) [E]" [b6]
Cc: "Hall, Matthew (NIH/NCATS) [E]" [b6]
Subject: Potential COVID targets for DD workshop

Hi Cliff,

In follow up of our conversation about this on the war room yesterday, I'm connecting you with Matt Hall, who is the NCATS lead on the potential COVID targets workshop we've been considering. We've envisioned this as a COVID version of the HEAL (opioid) targets meeting co-run by NCATS, NIDA, and NINDS a few years back: <https://ncats.nih.gov/pubs/features/heal-symposium>. Another model would be the COVID mAb workshop FNIH ran. Given that Tony promised D Birx he would see that a workshop happened, I don't want to step on toes. How do you suggest we move forward on a symposium perhaps co-run by NIAID, NCATS, and FNIH?

Chris

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Friday, September 4, 2020 3:46 PM
To: Austin, Christopher (NIH/NCATS) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD)

[E] [b6]

Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]

Subject: Re: Call with Dr. Birx

The way we left the call was that Tony would take responsibility for a follow-up. I think if there is something being planned for the near future that would cover it.

Cliff

From: "Austin, Christopher (NIH/NCATS) [E]" [b6]

Date: Friday, September 4, 2020 at 3:43 PM

To: "Lane, Cliff (NIH/NIAID) [E]" [b6]; "Wholley, David (FNIH) [T]" [b6];
"Collins, Francis (NIH/OD) [E]" [b6]; Lawrence Tabak [b6]; "Freire,
Maria (FNIH) [T]" [b6]; "Parker, Ashley (NIH/OD) [E]" [b6]; "Anderson,
James (NIH/OD) [E]" [b6]

Cc: Anthony Fauci [b6]

Subject: RE: Call with Dr. Birx

Hi Cliff,

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Best

Chris

From: Lane, Cliff (NIH/NIAID) [E] [b6]

Sent: Friday, September 4, 2020 2:15 PM

To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak,
Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher
(NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James
(NIH/OD) [E] [b6]

Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]

Subject: Call with Dr. Birx

ACTIV War Room colleagues,

Tony (copied), Janet, myself and several other just finished a call with Dr. Birx focused on the current state of therapeutics. One action item out of that call was to convene a "workshop" on targeted drug discover for SARS-CoV-2 similar to what had been done in the past for HIV (polymerase; protease, etc.). It would seem like this might be a good task for ACTIV Team 1 and Tony (copied) asked that I send this note. An alternative would be to do a workshop such as was recently done for the MoAb.

Dr. Birx also had a specific request as to whether or not ACTIV has vetted inhibitors of the bradykinin pathway and I sent a note to Sarah Read with this question.

Thanks,

Cliff

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/28/2020 1:34:52 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: RE: Collins letter to IRB Chair

Ditto!

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, August 27, 2020 9:26 PM
To: Collins, Francis (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6] Wood, Gretchen (NIH/OD) [E] [b6]
Subject: RE: Collins letter to IRB Chair

Thank you, Francis!

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 9:24 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Collins letter to IRB Chair

Sure, see attached.

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, August 27, 2020 8:45 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6] Wood, Gretchen (NIH/OD) [E] [b6]
Subject: FW: Collins letter to IRB Chair

Francis, please see below. Would it be possible to do this? Thanks much, David

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, August 27, 2020 5:21 PM
To: Wholley, David (FNIH) [T] [b6]

Cc: Menetski, Joseph (FNIH) [T] [b6]

Subject: FW: Collins letter to IRB Chair

Hi David,

ACTIV-3 would like to take Francis up on his offer to also do an IRB letter for them as he did for ACTIV-2. Attached is the draft of the ACTIV-3 letter based on the final version of the ACTIV-2 letter.

Would you ask Francis to sign this one, as well?

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Jim Neaton [b6]

Sent: Thursday, August 27, 2020 3:18 PM

To: Adam, Stacey (FNIH) [T] [b6]

Subject: Re: Collins letter to IRB Chair

now the attachment

From: Jim Neaton [b6]

Sent: Thursday, August 27, 2020 7:47 AM

To: Adam, Stacey (FNIH) [T] [b6]

Subject: Collins letter to IRB Chair

Hi Stacey - there is some interest in the letter to IRB chairs from Francis Collins. How will this work? Would you like addresses to send the letter?

Thanks.

Jim

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/9/2020 10:47:17 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200909.pptx
Attachments: ACTIV Daily Update 20200909.pptx

Slides for this morning's war room call, Wednesday, September 9.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/9/2020 1:34:50 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: FW: Government Employee Awareness
Attachments: UCLA_OWS_36720_OWS_Male_Ad_Lobs_ENG_v0.png; UCLA_OWS_36720_OWS_Female_Ad_Lobs_ENG_v0.png; ACTIV-2 Study -Study Introduction -04-September-2020 - V1.0.pdf; ACTIV-2 Study - HCP Referral Letter - 04-September-2020 - V1.0.pdf

Francis,

I assume this is part of the effort that you referenced in today's ACTIV EC prep call that includes John Burklow, Christine Shrive (sp?) of OWS, and Michael Pratt of HHS. In any event, FYI. David

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Tuesday, September 8, 2020 9:26 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Santos, Michael (FNIH) [T] [b6]; Chen, Helen Q. <qingchen@deloitte.com>
Subject: FW: Government Employee Awareness

Hi David,

FYI for the War Room in the AM.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct [b6] Mobile [b6]

From: Kim, Peter (NIH/NIAID) [E] [b6]
Sent: Tuesday, September 8, 2020 8:17 PM
To: Wohl, David A [b6]; Rhonda Henry [b6]
Cc: Davey Smith [b6]; Judy Currier [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Erhardt, William (HHS/IOS) [b6]; Marston, Hilary (NIH/NIAID) [E]

[b6]; Read, Sarah (NIH/NIAID) [E] [b6]

Subject: FW: Government Employee Awareness

FYI.

Stacey, Hilary, not sure if NIH and NIAID OD needs to be kept abreast of this, but Sec. Azar's team has agreed to highlight ACTIV-2 in this week's email to HHS. Below is what we sent in.

From: Kim, Peter (NIH/NIAID) [E] [b6]

Sent: Tuesday, September 8, 2020 8:11 PM

To: Bugin, Kevin (FDA/CDER) [b6]; Erhardt, William (HHS/IOS) [b6]

Cc: Kim, Peter (NIH/NIAID) [E] [b6]

Subject: RE: Government Employee Awareness

Kevin, thanks again for making the connections with Sec. Azar's team on this. Please find below some points that could be used to for Sec. Azar's message. I've also attached some documents that his team may find useful, either for informational purposes or to send out along with the message. The 2 PDFs are pending IRB approval tomorrow. Will confirm once that's done.

Peter

- Finding a COVID-19 vaccine will be important but, we also need safe and effective treatments for early COVID-19 for those who do get sick. Together, vaccines and treatments will get us to the end of this pandemic.
- The ACTIV-2 study is the flagship U.S. Government sponsored study to develop new, promising treatments for patients with COVID-19 in an outpatient setting (non-hospitalized). This is the largest outpatient treatment trial for COVID-19 and the one with the greatest promise of identifying the most effective and safest treatments.
- HHS is seeking your help to help raise awareness of this critical trial. Treatments for COVID-19 are likely to work best early in the infection course, so it's important that people know about the trial even before they are sick.
- The scientific leadership at NIH believe that the treatments being evaluated in ACTIV-2 have great potential to save lives, improve clinical outcomes of those with COVID-19 and even limit transmission of the infection by curtailing the disease course.
- The study is now open and we are doing our best to urgently enroll as many patients as possible to speed the development of these treatments. The number of treatments we are able to develop is dependent on the number of volunteers we get for our study. The more volunteers there are, the more treatments we can develop. Only with the help of those recently diagnosed with COVID-19 can we find the treatments that will help resolve symptoms and prevent people from needing to be hospitalized.
- Visit the website www.riseabovecovid.org, spread the word and be a part scientific process to bring this pandemic to an end!

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/31/2020 11:02:54 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200831.pptx
Attachments: ACTIV Daily Update 20200831.pptx; ACTIV-2 and -3 Accrual Enhancement Discussion 8-28-20.docx

Please see attached slides for today's war room meeting, Monday August 31, as well as a document describing the outcome of Friday evening's call with the ACTIV-2 and ACTIV-3 teams to address accrual issues ("site survey," Etc.)

From: Anderson, James (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]
Sent: 8/26/2020 12:43:10 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ACTIV Daily Update 20200826.pptx

All,

Can we predict how long the trials will continue? The tribes have little sense of urgency about participating. Their process for enrolling in research is deliberative, requires negotiation and thus is typically slow. I have encouraged Dave Wilson to focus his energy on the handful of tribes now willing to talk and less energy on continuing to identify potentially interested tribes. If it takes a year to enroll a tribe that is not realistic. The data sharing agreement for the Navajo Birth Cohort in ECHO took also 4 years to negotiate.

A sense of the timeframe would be helpful in engaging tribes and focusing the effort.

Thanks

Jim

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 26, 2020 7:41 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: ACTIV Daily Update 20200826.pptx

Slide for this morning's call, Wednesday August 26

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 9/9/2020 4:54:48 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: DRAFT NIH and ACTIV Clinical Trial Grid

Hi Ashley and David,

Great, thanks!

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, September 9, 2020 12:53 PM
To: Wholley, David (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]
Cc: Chen, Helen Q. <qingchen@deloitte.com>; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: DRAFT NIH and ACTIV Clinical Trial Grid

Mike you have the green light from David.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, September 9, 2020 12:46 PM
To: Santos, Michael (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Chen, Helen Q. <qingchen@deloitte.com>; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: DRAFT NIH and ACTIV Clinical Trial Grid

I agree with Mike. As long as it says do not copy or distribute and we emphasize that on the call I think we are OK>

From: Santos, Michael (FNIH) [T] [b6]
Sent: Wednesday, September 9, 2020 12:38 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Chen, Helen Q. <qingchen@deloitte.com>; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: DRAFT NIH and ACTIV Clinical Trial Grid

Hi Ashley,

Thanks. I believe that the Tx Working Group already knows that level of information about ACTIV-1 and ACTIV-5. Recognizing that in some cases they may not know all of the NIH IC plans, the level of information in the matrix seems

like it may be minimal enough to be comfortable sharing with the Working Group so that we can get their feedback, with of course a statement that this information is private and should not be discussed further.

Would you be amenable to that?

Best regards,
Mike (helping out Stacey and Helen for the week)

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] <[b6]>
Sent: Wednesday, September 9, 2020 12:13 PM
To: Adam, Stacey (FNIH) [T] <[b6]>
Cc: Wholley, David (FNIH) [T] <[b6]>; Santos, Michael (FNIH) [T] <[b6]>; Chen, Helen Q. <qingchen@deloitte.com>
Subject: Re: DRAFT NIH and ACTIV Clinical Trial Grid

Hi Stacey,

This version doesn't have the names of any compounds that will be tested in trials that haven't launched yet but does display ACTIV-1, ACTIV-5, and NIH ICs that plan to launch trials in the various categories (mAbs, other therapies, etc.).

If we are at all concerned that the names of the ACTIV 1,5 and NIH trials with the types of compounds that will be tested should not be released publicly yet I would say do not share ahead given we can not guarantee the information will not leak.

Thanks,
Ashley

On Sep 9, 2020, at 11:43 AM, Adam, Stacey (FNIH) [T] <[b6]> wrote:

Hi Ashley and David,

Can we present this to our TX-Clinical WG team members ahead of our meeting tomorrow, so we can ensure a productive feedback discussion of what they think is missing?
Or can this not be sent around broadly yet?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] <[b6]>
Sent: Tuesday, September 8, 2020 12:54 PM
To: Wholley, David (FNIH) [T] <[b6]>; Adam, Stacey (FNIH) [T] <[b6]>
Menetski, Joseph (FNIH) [T] <[b6]>
Cc: Freire, Maria (FNIH) [T] <[b6]>; Collins, Francis (NIH/OD) [E] <[b6]>

Tabak, Lawrence (NIH/OD) [E] [b6] Lane, Cliff (NIH/NIAID) [E]
[b6] Austin, Christopher (NIH/NCATS) [E] [b6] Anderson, James
(NIH/OD) [E] <[b6]>
Subject: DRAFT NIH and ACTIV Clinical Trial Grid

Good afternoon,

I hope everyone had a great holiday. I know there was interest from the Tx clinical WG to review the NIH and ACTIV clinical trial grid. Attached is a version that does not display agents/trial information that has not yet launched but has a placeholder for those trials "coming soon."

Please note this is still a working draft as we continue to add trials as they launch (agents for ACTIV-4 inpatient trial will be included once the trial launches this week).

We standby for any major edits the WG may have.

Thanks,
Ashley

<DRAFT ACTIV Checkerboard_9.4.20.pptx>

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 8/28/2020 5:57:21 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: rapid diagnostic testing for ACTIV trials

Is this a solved problem with the Abbott ID NOW instruments and cartridges, or do we need more help?

FC

From: Pao, William [b6]
Sent: Friday, August 28, 2020 1:54 PM
To: Collins, Francis (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6] Matt Sause [b6]
Subject: rapid diagnostic testing for ACTIV trials

Dear Francis and David,
I wanted to introduce you to Matt Sause, Pres & CEO for North America, Roche Diagnostics Corp.

I let him know that there have been delays in enrollment on the ACTIV trials due to slow turnaround times on testing. Roche may be able to help, so I'm putting you in touch with him.

Matt - Francis heads up NIH, and David heads up the FNIH, and they are running the ACTIV effort to help develop promising treatments for COVID-19.

I'll leave it to you all to f/u.

Best,
William

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/27/2020 7:05:09 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

I agree. This may actually be a good tool for making sure some of these efforts don't end up overlapping, as we heard on the call.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 3:03 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Next week is fine.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 2:57 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Yes, we can do this. How soon would you need it?

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 2:28 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

This is looking good. Thinking about a way to make this of wider use without disclosing confidential information, is there a version of this grid that could have the hot links provided for trials that have already been publicly announced, but a "coming soon" link for the others?

FC

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Thursday, August 27, 2020 2:23 PM

To: Collins, Francis (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6] Freire, Maria (FNIH) [T] [b6]

Cc: George, Jill (NIH/OD) [E] [b6] Adam, Stacey (FNIH) [T] [b6]

Subject: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Francis, David, and Maria,

With many thanks to Jill, attached is a PDF version of the CT grid without the links to the confidential agents etc.

I hear the Clinical Tx WG is interested in reviewing and providing edits/additions. If the ACTIV-4/NHLBI reps on the WG would like to make changes they should work closely with Amy Patterson – the current info provided was vetted by Amy and her team.

Once the WG group has collective edits we will update those on the live version. Please let us know if this plan works for FNIH—cc'ing Stacey as well.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/9/2020 3:54:53 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Question about recently viewed senate testimony

Hi Ashley and Francis,

Just a quick note. This current review of Ivermectin is actually the third time the Agent Prioritization team has reviewed the agent. We are doing so now because of some of the emerging data. Francis, we will share that you received this note when we are adjudicating the agent.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: (b6) Mobile: (b6)

From: Parker, Ashley (NIH/OD) [E] (b6)
Sent: Wednesday, December 9, 2020 10:48 AM
To: Collins, Francis (NIH/OD) [E] (b6)
Cc: Wholley, David (FNIH) [T] (b6); Adam, Stacey (FNIH) [T] (b6)
Subject: RE: Question about recently viewed senate testimony

Hi Francis,

As of 12/2 ivermectin is still under review for consideration in ACTIV-2, please see attached.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] (b6)
Sent: Wednesday, December 9, 2020 10:39 AM
To: Parker, Ashley (NIH/OD) [E] (b6)
Cc: Wholley, David (FNIH) [T] (b6); Adam, Stacey (FNIH) [T] (b6)
Subject: FW: Question about recently viewed senate testimony

Hi Ashley,

See attached and below. Didn't the ACTIV prioritization group look at ivermectin? Is there anything here that should cause a reconsideration?

FC

From: Hardie, Thomas [b6]
Sent: Wednesday, December 9, 2020 9:39 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Question about recently viewed senate testimony

Dear Dr, Collins

I met you briefly when I was part of the NINR program in the summer of 2000. I am a retired full professor of Nursing from the University of Delaware and an adjunct full professor at the Univ. of Penn. Yesterday I watched the testimony of Pierre Kory, MD before the US Senate pleading for the NIH to review his submitted preprint of a meta analysis of the use of ivermectin for the treatment of COVID-19. I have attached his testimony for your review. I was shocked by his statement that to his knowledge there were no NIH panels reviewing existing treatments for COVID-19. If this is true, it is disheartening. I have read the preprint and believe it identifies a significant signal for the effectiveness of ivermectin. I have been an author, coauthor and reviewer on numerous database publications which is the basis of my conclusion. I am surprised that NIH would wait for the peer reviewers of Science before considering the meta analysis information to revise their treatment recommendation for early COVID-19. I am sure the NIH faculty can independently review the preprint and provide comment and guidance. If my conclusion or Dr. Cory's analysis are incorrect I would encourage the NIH to explain this to the treatment community. If the meta analysis is correct please pressure those responsible at the NIH to act with greater urgency as many of us may die waiting. The guiding principle of do no harm appears to be outweighed by the evidence in the meta analysis if it is correct. The current NIH recommendation from 8/202 appears to be go home and don't call me until you have trouble breathing. I am concerned that this recommendation may be a contributing factor in countries like India having lower case fatality rates than the US. Thank you for hearing my concerns.

Respectfully

Dr. Thomas L. Hardie NP RN
Sent from [Mail](#) for Windows 10

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/20/2020 8:34:53 PM
To: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
Subject: FW: ACTIV Leadership Pre-call
Attachments: 10.21 ACTIV Leadership Team Meeting 20201016.pdf

Draft slides attached with final slides forthcoming.

From: Gonzalez, Nina <ningonzalez@deloitte.com>
Sent: Friday, October 16, 2020 1:31 PM
To: Melencio, Cheryl (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Margaret Anderson <marganderson@deloitte.com>; Chen, Helen Q. <qingchen@deloitte.com>; Elsaid, Olivia <elsaid@deloitte.com>; Hawk, Harrison <hhawk@deloitte.com>; Santos, Michael (FNIH) [T] [b6]; Stratton, Benjamin <bstratton@deloitte.com>; btolman <btolman@deloitte.com>; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@DELOITTE.com>
Cc: Wood, Gretchen (NIH/OD) [E] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6]
Subject: RE: ACTIV Leadership Pre-call

All -

Apologies for the delay, please see attached the slides we will discuss at 1:30pm.

Thank you,

Nina Gonzalez

Nina Gonzalez
Deloitte Consulting LLP
Tel/Direct: 202 748 6535
ningonzalez@deloitte.com | www.deloitte.com

Please consider the environment before printing

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Tuesday, August 18, 2020 11:14 AM
To: Melencio, Cheryl (FNIH) [T]; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Alvarez, Rosa Maria; Anderson, Margaret; Chen, Helen Q.; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Santos, Michael (FNIH) [T]; Stratton, Benjamin; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan
Cc: Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]
Subject: ACTIV Leadership Pre-call

APAR0000020885

When: Friday, October 16, 2020 1:30 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: see webex below

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/20/2020 8:08:20 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Agenda for Leadership Team ACTIV Call

OK, thanks!

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Tuesday, October 20, 2020 4:07 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Agenda for Leadership Team ACTIV Call

The agenda and materials will go out shortly.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, October 20, 2020 4:05 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: Agenda for Leadership Team ACTIV Call

Hi Cheryl,

One of my colleagues was asking about the agenda for tomorrow – do you have a copy?

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the Chief of Staff and NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 12/9/2020 7:58:52 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: Accepted: ACTIV Vaccines Working Group meeting
Location: <https://fnih.zoom.us/j/91812345678> **b6**
Start: 12/14/2020 5:00:00 PM
End: 12/14/2020 6:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/30/2020 1:15:11 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV Call "War Room"

Location: Dial-In: [b6] Passcode: [b6]

Start: 12/4/2020 1:00:00 PM

End: 12/4/2020 1:30:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/9/2020 7:10:15 PM
To: Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponeim]
Subject: RE: ACTIV clinical trial protocol links

Hi Emma,

At a glance we added links to the ACTIV protocols – great! We will follow up if there are any edits.

Thank you,
Ashley

From: Wojtowicz, Emma (NIH/OD) [E] [b6]
Sent: Monday, November 9, 2020 12:31 PM
To: Myles, Renate (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: ACTIV clinical trial protocol links

Hi Ashley and Lauren-

The ACTIV Therapeutics page is updated: <https://www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials>. Please review and let us know if you have any edits or concerns.

Thanks-
Emma

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, November 6, 2020 5:45 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] Wojtowicz, Emma (NIH/OD) [E] [b6]
Subject: RE: ACTIV clinical trial protocol links

Thanks, Ashley. Yes, Greta just shared them just now and we're going to add them to the ACTIV pages on Monday.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, November 6, 2020 5:43 PM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: Fwd: ACTIV clinical trial protocol links

FYI

Begin forwarded message:

From: "Freire, Maria (FNIH) [T]" [b6]

Date: November 6, 2020 at 5:16:47 PM EST

To: "Collins, Francis (NIH/OD) [E]" [b6] "Tabak, Lawrence (NIH/OD) [E]"

[b6] "Lane, Cliff (NIH/NIAID) [E]" [b6] "Anderson, James (NIH/OD) [E]" [b6] "Austin, Christopher (NIH/NCATS) [E]"

[b6] "Wholley, David (FNIH) [T]" [b6] "Parker, Ashley (NIH/OD) [E]" [b6]

Subject: ACTIV clinical trial protocol links

Francis, as mentioned this morning, below are the links to the ACTIV protocols. Six of the seven are now available, and Stacey should send us the last one soon. Renate should have these forthwith. Best, M.

<https://fnih.org/what-we-do/programs/activ-partnership#activ1>

<https://fnih.org/what-we-do/programs/activ-partnership#activ2>

<https://fnih.org/what-we-do/programs/activ-partnership#activ3>

<https://fnih.org/what-we-do/programs/activ-partnership#activ4a>

<https://fnih.org/what-we-do/programs/activ-partnership#activ4b>

<https://fnih.org/what-we-do/programs/activ-partnership#activ4c>

<https://fnih.org/what-we-do/programs/activ-partnership#activ5>

Maria C. Freire, Ph.D.

President and Executive Director

Foundation for the National Institutes of Health

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

[b6] fnih.org



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/2/2020 4:30:42 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV EC & WG Co-chair Pre-call
Location: see webex below
Start: 11/2/2020 9:45:00 PM
End: 11/2/2020 10:15:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/30/2020 1:15:03 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV Call "War Room"

Location: Dial-In: Passcode:

Start: 12/2/2020 1:00:00 PM

End: 12/2/2020 1:30:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/4/2020 10:47:13 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Stacey,

Got it – thank you!

Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 5:39 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Ashley,

Please find the updated slides with the changes and appropriate file labels.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, November 4, 2020 5:20 PM
To: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Sorry, catching up on emails. I will standby for the revised versions.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 5:19 PM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Thanks, David,

I will also change that too.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 5:17 PM
To: Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

The slide titles should also make it clear for Francis which is for presentation and which just for private reference. I don't think the current titles accomplish that.

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 4:21 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Ashley,

My apologies we just caught an slight error in both slide sets. Please use these but the descriptions below still apply.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Wednesday, November 4, 2020 4:09 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Ashley,

My apologies. I have slides I just have not had a chance to send them to you yet.

Please see attached two versions. One version is a simplified summary that FC can use to present. The second version is the full summary of agents and where they ranked. This second one cannot be presented in a public forum, but we wanted FC to have it in case he gets questions.

David, do you think this is an acceptable solution to your early concern about making the compounds reviewed public?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E]: [b6]
Sent: Wednesday, November 4, 2020 3:07 PM
To: Adam, Stacey (FNIH) [T]: [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Stacey,

Just checking to see if we are on schedule to receive the ACTIV antiviral summary slide today. Francis has requested that I send the complete package by COB today.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T]: [b6]
Sent: Monday, November 2, 2020 11:35 AM
To: Wholley, David (FNIH) [T]: [b6] Parker, Ashley (NIH/OD) [E]: [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi David,

You raise good point. We have made it a policy not to show which agents we have reviewed and where we have placed them to the public, as it could have market effects. I had for a moment forgotten this Summit would be public. We had shared the details with Hever. I will work with Evan to get something at the right level for summary.

As for the Merck drug, I just sent you another email as requested.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Wholley, David (FNIH) [T]: [b6]
Sent: Monday, November 2, 2020 10:19 AM
To: Parker, Ashley (NIH/OD) [E]: [b6] Adam, Stacey (FNIH) [T]: [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Stacey, the question also is whether this is something Francis can show the Summit attendees. If not, we need to signal that and describe what he can show. In addition, Francis asked this morning if we know anything about what is going on

with the Merck/Ridgeback drug and whether Merck is/would consider bringing it into any of the ACTIV protocols. You can send me that under separate cover when you get the chance. Thanks, David

From: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>

Sent: Monday, November 2, 2020 8:27 AM

To: Wholley, David (FNIH) [T] [REDACTED] b6 [REDACTED]; Adam, Stacey (FNIH) [T] [REDACTED] b6 [REDACTED]

Subject: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Good morning David and Stacey,

David, per the conversation on the war room call this morning – attached is the slide Francis would like to have updated for his presentation for the NIH Antiviral Tx Summit on Friday, 11/6.

Looping in Stacey as requested. Francis has requested an updated draft by Wed, 11/4 – hopefully this works for the FNIH team.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the Chief of Staff and NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health

Tel: [REDACTED] b6 [REDACTED]



National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/30/2020 1:14:41 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV Call "War Room"

Location: Dial-in: Passcode:

Start: 12/7/2020 1:00:00 PM

End: 12/7/2020 1:30:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/25/2020 5:01:04 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV Leadership Call #10
Location: <https://fnih.zoom.us> b6
Start: 11/19/2020 5:00:00 PM
End: 11/19/2020 6:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 12/11/2020 7:34:00 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV Call "War Room"

Location: Dial-In: [b6] Passcode: [b6]

Start: 12/7/2020 1:00:00 PM

End: 12/7/2020 1:30:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 12/2/2020 2:47:42 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Updates to ACTIV Master List

Got it – thanks!

Ashley

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, December 2, 2020 8:53 AM
To: Parker, Ashley (NIH/OD) [E] [b6], Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Updates to ACTIV Master List

We have approvals for listing on website:

Kent Lloyd, DVM, PhD
Professor, Department of Surgery, School of Medicine
Director, Mouse Biology Program
Associate Director, Comprehensive Cancer Center
UC Davis Mouse Biology Program

Joanne Lumsden, Ph.D.
Senior Scientific Program Manager, Drug Development Partnership Programs
National Center for Advancing Translational Sciences, NIH

Thank you

Cheryl
Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
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From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Wednesday, December 2, 2020 8:34 AM

To: Melencio, Cheryl (FNIH) [T] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]

Subject: RE: Updates to ACTIV Master List

Thanks, Cheryl! We will standby to include their information on the website.

I hope you are great holiday as well.

Ashley

From: Melencio, Cheryl (FNIH) [T] [b6]

Sent: Tuesday, December 1, 2020 5:47 PM

To: Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]

Subject: Updates to ACTIV Master List

Dear Ashley and Lauren

I hope you had a nice Thanksgiving holiday. I have made two additions to the master list for the preclinical working group. I have sent emails asking for their permission to list them on the website.

Kent Lloyd, DVM
University of California at Davis

Joanne Lumsden
NCATS

Take care

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/8/2020 11:22:07 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]
Subject: Re: ACTIV papers

That would be a Renate question but I've asked OCPL to post on the ACTIV website.

Thanks,
Ashley

On Oct 8, 2020, at 5:46 PM, Menetski, Joseph (FNIH) [T] [b6] wrote:

I wonder if there is any interest to have them out on social media, maybe in a post by Dr Collins?

Joe

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, October 8, 2020 3:50 PM
To: Menetski, Joseph (FNIH) [T] [b6]
Cc: Colvis, Christine (NIH/NCATS) [E] [b6]
Subject: RE: ACTIV papers

Thanks, Joe. I will work on getting these publications added to the ACTIV website.

Thanks,
Ashley

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Thursday, October 8, 2020 1:29 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6] Colvis, Christine (NIH/NCATS) [E] [b6]
Subject: FW: ACTIV papers

Ashley,

Just an FYI that these papers have been published from the ACTIV preclinical group

Joe

Subject: ACTIV papers

ACTIV papers from the Preclinical WG in Cell Host and Microbe

Accelerated preclinical paths to support rapid development of COVID-19 therapeutics

[https://www.cell.com/cell-host-microbe/fulltext/S1931-3128\(20\)30522-9](https://www.cell.com/cell-host-microbe/fulltext/S1931-3128(20)30522-9)

ACTIVating Resources for the COVID-19 Pandemic: In vivo Models for Vaccines and Therapeutics

[https://www.cell.com/cell-host-microbe/fulltext/S1931-3128\(20\)30521-7](https://www.cell.com/cell-host-microbe/fulltext/S1931-3128(20)30521-7)

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

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<image001.jpg> <image002.jpg> <image003.jpg> <image004.jpg>

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<image005.png>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 12/11/2020 7:33:53 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: January ACTIV Pre-call
Location: see webex below

Start: 1/19/2021 6:30:00 PM
End: 1/19/2021 7:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/28/2020 9:18:42 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]
CC: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Lohmann, Larry (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f4206cbb2c4d82adbc1eda15e035c4-lohmannll]; Berkson, Laura (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=adb561ab47e54fdc94e2a54682514434-berksonid]
Subject: RE: COVID-19 preclinical research - ACTIV

Hi Joe,

Thank you and Christine for the response below. We will follow up if there are any additional questions.

Thanks,
Ashley

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Monday, September 28, 2020 11:44 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]
Cc: Anderson, James (NIH/OD) [E] [b6]; Lohmann, Larry (NIH/OD) [E] [b6]; Berkson, Laura (NIH/OD) [E] [b6]
Subject: RE: COVID-19 preclinical research - ACTIV

Dear Ashley,

Does this cover your questions and needs? Please let us know if there is anything else we can do.

Currently, ACTIV does not have funding to support research. With regard to animal models, the role that ACTIV has taken is to provide information and guidance to the research with regard to which models are appropriate for which types of studies. We also have a portal through which researchers may submit their agent (generally small molecule, but biologics have been submitted) information for consideration for testing in one of the ACTIV clinical trials. For agents that look promising, but need additional animal studies, the submitter is notified and asked if they have the ability to conduct the studies or need assistance. Thus far, most cases have been able to use small animals, which are not limited in supply, although there may be some limitations in ABSL3 space. If they need assistance, we connect them to the NIAID staff who manage contracts for such studies. If they have the financial resources to pay for studies, we connect them to one of the sites that has fee for service capabilities and capacity. So far we have guided 6 assets through the initial stages of match making, 2 assets came from public sources (NIH and academic PIs) while 4 were associated with small biotech companies. Overall there are an additional 15 assets that are in line to go through the match-making process, 4 of those are from public sources (NIH and academic PIs) and 11 are from industry sponsors (small and large biotech). Access to facilities where funding is available (generally through NIAID) is very limited (2-3 facilities) and the backup in testing is substantial (1-2 compounds per month, over 10 compounds are waiting). We are trying to guide sponsors to other contract organizations, but not all sponsors have the ability to support the preclinical studies needed.

Since ACTIV does not have funding to support research, projects that need NHPs are directed to submit their proposal (regardless of funding source) to <https://redcap.ncats.nih.gov/redcap/surveys/?s=TLX93TDDMR>. In general before any

NHPs will be used, small animal studies would be conducted first to avoid unnecessary use of the NHPs. Thus far, the primary focus for NHPs has been on vaccine development, which is primarily being directed by OWS. That said, ACTIV has not seen requests for NHP studies from OWS. Because of the limited number of NHPs and the lack of a validated model for inflammatory response to SARS-CoV2 in these animals, we have only suggested 1 asset for NHP testing. We have also been encouraging validation studies with NHPs to model the inflammatory sequelae induced by SARS-CoV2, particularly in the African Green Monkey. ACTIV has played a key role in ensuring that the NHP studies conducted at the NPRCs are harmonized to allow sharing of control animals across different studies (which will reduce the total number of animals needed) and that they are aligned with the ACTIV master protocols to make it easier to compare between human trials and NHP studies.

Best regards,
Joe (and Christine)

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, September 24, 2020 11:25 AM
To: Colvis, Christine (NIH/NCATS) [E] [b6]
Cc: Anderson, James (NIH/OD) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Lohmann, Larry (NIH/OD) [E] [b6]; Berkson, Laura (NIH/OD) [E] [b6]
Subject: Re: COVID-19 preclinical research - ACTIV

Hi Christine,

I received the note below asking me to coordinate the response to the follow up questions from the briefing you had with the House Minority Committee on Tuesday regarding the ACTIV preclinical WG.

We can provide the committee with a link to the ACTIV website for the preclinical WG roster however OLPA needs responses to the remaining questions.

Could we please have responses to these questions by Monday, 9/28? Cc'ing Jim and Joe per the note below.

1. Rosters of the preclinical working group and the committee prioritizing requests (Committee will treat as non-public close holds); <https://www.nih.gov/research-training/medical-research-initiatives/activ/preclinical-working-group#members>
2. The number of companies that ACTIV has assisted with ABSL-3 lab space requests;
3. The number of companies that ACTIV has assisted with animal model requests; and
4. Which supply of animals is so limited that going overseas is necessary.

Thanks,
Ashley

From: Lohmann, Larry (NIH/OD) [E] [b6]
Sent: Thursday, September 24, 2020 10:41 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Berkson, Laura (NIH/OD) [E] [b6]
Subject: Re: COVID-19 preclinical research - ACTIV

Good morning Ashley,

Dr. Anderson recommended Christine Colvis w/NCATS for this briefing that was held on 9/22. Dr. Colvis did a fantastic job, but there were a few follow-up questions that still need to be answered for E&C Minority staff. Dr. Colvis believed most of the unanswered questions could be answered by Jim Anderson or Joe Menetski. Could you please help me round up the information for the items below so I can respond to the committee?

Very respectfully,
Larry Lohmann

Larry Lohmann, Esq.
Office of Legislative Policy & Analysis
National Institutes of Health

b6

b6

C/telework

Rosters of the preclinical working group and the committee prioritizing requests (Committee will treat as non-public close holds);

The number of companies that ACTIV has assisted with ABSL-3 lab space requests;

The number of companies that ACTIV has assisted with animal model requests; and

Which supply of animals is so limited that going overseas is necessary.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/4/2020 10:19:03 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6
Attachments: ACTIV Antiviral Summary Slide 11_6_20_Preclinical and Clinical Updates- v3 (1).pptx; ACTIV Antiviral Summary Slide 11_6_20_Preclinical and Clinical Updates- v4.pptx

Hi Stacey,

To ensure I've got this right vs.3 is for FC's background only (I can make the edit on the first slide and change 9 agents to 8 agents). Include both slides in V4 which means it's okay to show the "Go" agents? If so, shouldn't we also show the 8 preclinical match-making agents?

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 4:21 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Ashley,

My apologies we just caught an slight error in both slide sets. Please use these but the descriptions below still apply.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Wednesday, November 4, 2020 4:09 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Ashley,

My apologies. I have slides I just have not had a chance to send them to you yet.

Please see attached two versions. One version is a simplified summary that FC can use to present. The second version is the full summary of agents and where they ranked. This second one cannot be presented in a public forum, but we wanted FC to have it in case he gets questions.

David, do you think this is an acceptable solution to your early concern about making the compounds reviewed public?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, November 4, 2020 3:07 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Stacey,

Just checking to see if we are on schedule to receive the ACTIV antiviral summary slide today. Francis has requested that I send the complete package by COB today.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, November 2, 2020 11:35 AM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi David,

You raise good point. We have made it a policy not to show which agents we have reviewed and where we have placed them to the public, as it could have market effects. I had for a moment forgotten this Summit would be public. We had shared the details with Hever. I will work with Evan to get something at the right level for summary.

As for the Merck drug, I just sent you another email as requested.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, November 2, 2020 10:19 AM

To: Parker, Ashley (NIH/OD) [E]; [b6] Adam, Stacey (FNIH) [T]; [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Stacey, the question also is whether this is something Francis can show the Summit attendees. If not, we need to signal that and describe what he can show. In addition, Francis asked this morning if we know anything about what is going on with the Merck/Ridgeback drug and whether Merck is/would consider bringing it into any of the ACTIV protocols. You can send me that under separate cover when you get the chance. Thanks, David

From: Parker, Ashley (NIH/OD) [E]; [b6]
Sent: Monday, November 2, 2020 8:27 AM
To: Wholley, David (FNIH) [T]; [b6] Adam, Stacey (FNIH) [T]; [b6]
Subject: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Good morning David and Stacey,

David, per the conversation on the war room call this morning – attached is the slide Francis would like to have updated for his presentation for the NIH Antiviral Tx Summit on Friday, 11/6.

Looping in Stacey as requested. Francis has requested an updated draft by Wed, 11/4 – hopefully this works for the FNIH team.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the Chief of Staff and NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/25/2020 5:00:27 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV EC & Working Group Co-Chair Meeting

Location: <https://fnih.zoom.us/j/92011111111> b6

Start: 11/4/2020 3:00:00 PM

End: 11/4/2020 4:00:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 12/9/2020 1:34:46 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: Re: Happy Thanksgiving
Flag: Follow up

Hi Carrie,

I am following up on the CVS, Michael Cohen request to meet with ICDs that was planned to be discussed at catch-up yesterday. Touching base regarding the decision and follow up reply to Michael?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Monday, December 7, 2020 1:55 PM
To: Wolinetz, Carrie (NIH/OD) [E] <[b6]> Parker, Ashley (NIH/OD) [E] <[b6]>
Cc: Freire, Maria (FNIH) [T] <[b6]> Adam, Stacey (FNIH) [T] <[b6]>
Subject: RE: Happy Thanksgiving

Thank you, Carrie.

From: Wolinetz, Carrie (NIH/OD) [E] <[b6]>
Sent: Monday, December 7, 2020 1:53 PM
To: Wholley, David (FNIH) [T] <[b6]> Parker, Ashley (NIH/OD) [E] <[b6]>
Cc: Freire, Maria (FNIH) [T] <[b6]> Adam, Stacey (FNIH) [T] <[b6]>
Subject: RE: Happy Thanksgiving

Thanks, David – we can respond directly to Michael. Cheers, Carrie

Carrie D. Wolinetz, Ph.D
Acting Chief of Staff and
Associate Director for Science Policy
Office of the Director
National Institutes of Health (NIH)
[b6]
<http://osp.od.nih.gov/>
Please follow on Twitter: @CWolinetzNIH



From: Wholley, David (FNIH) [T] <[b6]>
Sent: Monday, December 7, 2020 11:53 AM
To: Wolinetz, Carrie (NIH/OD) [E] <[b6]> Parker, Ashley (NIH/OD) [E] <[b6]>

Cc: Freire, Maria (FNIH) [T] <[b6]>; Adam, Stacey (FNIH) [T] <[b6]>

Subject: FW: Happy Thanksgiving

Hi Carrie and Ashley:

As you know, CVS has been working with several NIH trials, including some ACTIV trials, on using their diagnostic and nursing services in order to provide referrals of COVID-19 positive patient or help with trial-related interventions. Shortly before Thanksgiving Michael Cohen reached out to FNIH via Stacey Adam to say that CVS has interest in providing these services, and perhaps others, more broadly to other NIH trials in other disease areas outside COVID. Via war room and other venues, I brought this request to Francis and Larry and asked how NIH wanted to handle it. Last I heard I thought there had been a discussion with the IC Directors and a conclusion reached to set up a call with interested ICs and CVS, but it appears from Michael's note below that no one from NIH has reached out. Rather than bother Francis or Larry directly I thought I would ask you what the status is, and whether you could respond directly to Michael's renewed request. Thanks, David

From: Adam, Stacey (FNIH) [T] <[b6]>

Sent: Monday, December 7, 2020 11:00 AM

To: Wholley, David (FNIH) [T] <[b6]>

Subject: FW: Happy Thanksgiving

FYI on CVS

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: <[b6]> Mobile: <[b6]>

From: Cohen, Michael J <[b6]>

Sent: Monday, December 7, 2020 9:40 AM

To: Adam, Stacey (FNIH) [T] <[b6]>

Subject: RE: Happy Thanksgiving

Hope you had a nice weekend. Just following up as no emails last week from those teams. Thank you for your help and championing CVS at NIH!

Best,
Michael

<[b6]>

Proprietary

From: Adam, Stacey (FNIH) [T] <[b6]>

Sent: Monday, November 30, 2020 12:32 PM

To: Cohen, Michael J <[b6]>

Subject: [EXTERNAL] RE: Happy Thanksgiving

**** External Email - Use Caution ****

Hi Michael,

Not that I know of, but I will keep you posted.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Cohen, Michael J [b6]

Sent: Monday, November 30, 2020 12:29 PM

To: Adam, Stacey (FNIH) [T] [b6]

Subject: RE: Happy Thanksgiving

Thank you greatly appreciated! Do you need anything from me?

Talk soon!

Best,

Michael

[b6]

Proprietary

From: Adam, Stacey (FNIH) [T] [b6]

Sent: Monday, November 30, 2020 12:27 PM

To: Cohen, Michael J [b6]

Subject: [EXTERNAL] RE: Happy Thanksgiving

**** External Email - Use Caution ****

Hi Michael,

I hope you had a great Thanksgiving, as well!

I am sorry that I did not follow up with you last week. The topic was discussed and there was general interest from many of the ICs. Dr. Collins staff is supposed to be reaching out to you to discuss further, as they wanted to be the ones to facilitate. If you don't hear by the end of the week, please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Cohen, Michael J [b6]

Sent: Monday, November 30, 2020 12:17 PM

To: Adam, Stacey (FNIH) [T] [b6]

Subject: Happy Thanksgiving

APAR0000021066

Hi Stacey,

Hope you had a Happy Thanksgiving!

Any updates from last week regarding Dr. Collins and how we can potentially work together outside of COVID?

Michael J Cohen (he/him/his)

Director, Pharmaceutical Commercialization

CVS Clinical Trial Services

m [REDACTED] b6
e [REDACTED] b6



Proprietary

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This e-mail may contain confidential or privileged information. If you think you have received this e-mail in error, please advise the sender by reply e-mail and then delete this e-mail immediately.

This e-mail may also contain protected health information (PHI) with information about sensitive medical conditions, including, but not limited to, treatment for substance use disorders, behavioral health, HIV/AIDS, or pregnancy. This type of information may be protected by various federal and/or state laws which prohibit any further disclosure without the express written consent of the person to whom it pertains or as otherwise permitted by law. Any unauthorized further disclosure may be considered a violation of federal and/or state law. A general authorization for the release of medical or other information may NOT be sufficient consent for release of this type of information. Thank you.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/7/2020 7:02:26 PM
To: Fritz, Craig (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79148d8c0cee49689fd637304bb82b42-fritzcm]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: Update on Forthcoming Rollouts

Got it – thanks!

From: Fritz, Craig (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 3:01 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

Sorry about that. Here it is.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 2:52 PM
To: Fritz, Craig (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

No attachment?

From: Fritz, Craig (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 2:46 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

And a revised ITAC. Still no GO time.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 2:44 PM
To: Fritz, Craig (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

OK, thanks!!

From: Fritz, Craig (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 2:10 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

Hi Ashley – still no CT identifier, but this is the latest.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 9:50 AM
To: Fritz, Craig (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

Thanks!!

From: Fritz, Craig (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 9:43 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

Hi Ashley,

Here's the latest ITAC release. Still waiting on concrete timing.

Thanks,
Craig

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 8:39 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Fritz, Craig (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

Hi Renate and Craig,

Do we have the draft release for the ITAC trial?

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, October 6, 2020 5:05 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Parker, Ashley (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]
McManus, Ayanna (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Seigfreid, Kim (NIH/OD) [E] [b6]
Schwetz, Tara (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]
Subject: Update on Forthcoming Rollouts

Good afternoon:

I wanted to provide an update on several forthcoming rollouts. As is always, this timing is tentative and subject to change. We'll keep you posted as we get more information.

Likely Oct. 7 or 8:

ITAC Hyperimmune Globulin (ACTIV-like)

Rollout:

- NIAID News Release
- Social Media

- Release is cleared

ACTIV-5 BET

Rollout:

- NIAID News Release only (no media telebriefing)
- Add to ACTIV Therapeutics page
- Release is cleared

Likely Thursday, October 15:

ACTIV-1 Immune Modulators

Rollout:

- Embargoed News Release
- Embargoed Media Advisory
- Release in clearance
- Embargoed Media Telebriefing (by phone only/no video)
 - Principals:
 - Francis Collins
 - Chris Austin
 - Paul Stoffels, Janssen
 - BMS spokesperson
 - AbbVie does not want to participate
 - Participants:
 - David Wholley
- Social media event

As early as October 19:

Novavax Phase 3 Vaccine

Rollout:

- Embargoed News Release
- Embargoed Media Advisory
- Embargoed Media Telebriefing (by telephone; no video)
 - Principals:
 - Francis Collins
 - Tony Fauci
 - Matt Hepburn
 - Novavax Spokesperson
- Social Media Event

December:

- Sanofi Phase 3 Vaccine Trial

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/15/2020 2:09:01 AM
To: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]
Subject: Fwd: 11/19 Leadership Team Agenda

FYI

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

Begin forwarded message:

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: November 14, 2020 at 6:53:56 PM EST
To: "Wholley, David (FNIH) [T]" [b6]
Cc: "Tabak, Lawrence (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: RE: 11/19 Leadership Team Agenda

That sounds right to me. I don't think I see a scheduled run through of the presentation before the LT meets on Thursday – but I'll look forward to that. The last couple of rehearsals have been a bit rough, maybe not quite ready yet. But I do like to see the plan before it happens.

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, November 13, 2020 7:42 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: 11/19 Leadership Team Agenda

Hi Francis, we will be working on slides for the next ACTIV LT meeting next week over the weekend and wanted to get your take on the attached agenda. On the Vaccines WG, we can try to see if Doug will respond but if not Mike Santos can outline the list of topics they are tackling. On clinical trial recruitment enhancement, the plan will be merely to highlight where we have made progress, rather than go through the whole long list of extant programs again. Could I please get your thoughts on this when you have 5 minutes to spare? Thanks, David

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 12/11/2020 7:17:28 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV Call "War Room"

Location: Dial-In: Passcode:

Start: 12/4/2020 1:00:00 PM

End: 12/4/2020 1:30:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/2/2020 1:40:42 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Thanks, Stacey!
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, November 2, 2020 8:40 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Thanks, Ashley,

We will take care of getting it updated, and we should have it to you by Wednesday, no issue. If there is any trouble, we will let you know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, November 2, 2020 8:27 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Good morning David and Stacey,

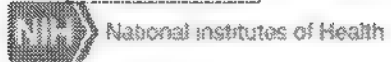
David, per the conversation on the war room call this morning – attached is the slide Francis would like to have updated for his presentation for the NIH Antiviral Tx Summit on Friday, 11/6.

Looping in Stacey as requested. Francis has requested an updated draft by Wed, 11/4 – hopefully this works for the FNIH team.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the Chief of Staff and NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health

Tel: b6



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 12/11/2020 7:17:17 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV Call "War Room"

Location: Dial-in: Passcode:

Start: 12/7/2020 1:00:00 PM

End: 12/7/2020 1:30:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/8/2020 8:22:00 PM
To: Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponeim]
Subject: RE: ACTIV papers

Thanks, Emma!

Ashley

From: Wojtowicz, Emma (NIH/OD) [E] [b6]
Sent: Thursday, October 8, 2020 3:59 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: ACTIV papers

Thanks, Ashley. NCATS told us about these and we were going to ask you if we should post. We will get these posted.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, October 8, 2020 3:53 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: Re: ACTIV papers

Hi Renate and Emma,

The preclinical WG has two recent publications. Can we please add these to the ACTIV publications page whenever you have a chance?

Accelerated preclinical paths to support rapid development of COVID-19 therapeutics

[https://www.cell.com/cell-host-microbe/fulltext/S1931-3128\(20\)30522-9](https://www.cell.com/cell-host-microbe/fulltext/S1931-3128(20)30522-9)

ACTIVating Resources for the COVID-19 Pandemic: In vivo Models for Vaccines and Therapeutics

[https://www.cell.com/cell-host-microbe/fulltext/S1931-3128\(20\)30521-7](https://www.cell.com/cell-host-microbe/fulltext/S1931-3128(20)30521-7)

Thank you,
Ashley

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Thursday, October 8, 2020 1:29 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]
Subject: FW: ACTIV papers

Ashley,

Just an FYI that these papers have been published from the ACTIV preclinical group

Joe

Subject: ACTIV papers

ACTIV papers from the Preclinical WG in Cell Host and Microbe

Accelerated preclinical paths to support rapid development of COVID-19 therapeutics

[https://www.cell.com/cell-host-microbe/fulltext/S1931-3128\(20\)30522-9](https://www.cell.com/cell-host-microbe/fulltext/S1931-3128(20)30522-9)

ACTIVating Resources for the COVID-19 Pandemic: In vivo Models for Vaccines and Therapeutics

[https://www.cell.com/cell-host-microbe/fulltext/S1931-3128\(20\)30521-7](https://www.cell.com/cell-host-microbe/fulltext/S1931-3128(20)30521-7)

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

b6 fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/25/2020 3:56:06 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV EC & WG Co-chair Pre-call
Location: see webex below
Start: 11/2/2020 9:15:00 PM
End: 11/2/2020 9:45:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/25/2020 3:44:38 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV Leadership Team Pre-call
Location: see webex below
Start: 11/17/2020 5:00:00 PM
End: 11/17/2020 5:30:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/24/2020 12:14:11 PM
To: Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2fbf13-walsher]
Subject: Fwd: Request for Further Information on Agent Submitted for Consideration for ACTIV Trials

FYI

Ashley Parker, Ph.D.

Office of the Director | National Institutes of Health

Tel: b6

Begin forwarded message:

From: "Adam, Stacey (FNIH) [T]" b6
Date: September 24, 2020 at 8:02:41 AM EDT
To: b6
Cc: "Chen, Helen Q." <qingchen@deloitte.com>
Subject: Request for Further Information on Agent Submitted for Consideration for ACTIV Trials

Dear Dr. Javitt,

It has come to our attention that you may not have received our first follow up email to your submission to the overarching ACTIV portal. We apologize for the inconvenience this may have caused. For therapeutics wishing to be considered, there is a second necessary step to be taken so we have the proper information for review.

In an effort to standardize and streamline collection and evaluation of relevant preclinical and clinical data, we have developed a survey to catalog therapeutic candidates. We would like to invite you to complete the survey and provide additional information about your agent.

Complete Survey Here: [ACTIV COVID-19 Clinical and Preclinical Candidate Compound Portal](#)

Please note that submission of a form is entirely voluntary and does not represent any kind of promise or commitment to consider for funding or actually provide funding for an agent or any activities associated with its development on the part of NIH or any of the ACTIV partners.

Please note that while we have tried to limit the amount of data requested to those key elements that are necessary for practical scientific evaluation of agents for further development, the level of detail required to do so is not trivial. Because of this, the form may take 1-2 hours to complete, depending on how much data a respondent has near to hand. For this reason the form has been designed so that it may be completed in stages, with a feature that allows users to save any partial data they have entered, quit and return to the survey at their convenience.

We welcome submissions from stakeholders throughout the biopharmaceutical, academic, scientific research, advocacy, clinical practice communities, and the general public. Please feel free to share this with your colleagues who may have promising agents for ACTIV to consider.

Thank you!
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: Mobile:

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNHI's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/24/2020 12:06:05 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]
Subject: Re: Inquiry from Portal Submitter Jonathan Javitt

Hi Stacey,

Thank you for the quick response! I will share this information with the OD team.

Thanks,
Ashley

On Sep 24, 2020, at 7:59 AM, Adam, Stacey (FNIH) [T] [b6] wrote:

Hi Ashley,

I told Nicole he had not applied because he had never responded to the RedCap Survey that we sent the link to. I don't know if it went to his spam folder or what, but I will resend the RedCap survey email to him again now.

Sorry for the glitch. We never know when they don't respond if they don't get it or they are just no longer interested.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, September 24, 2020 7:46 AM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: Re: Inquiry from Portal Submitter Jonathan Javitt

Hi Stacey,

Please see the attached note from Jonathan Javitt

[b6]. The attachments suggests his submissions was sent to FNIH — not sure if he was sent the RedCap survey but someone (OWS?) let him know the submission was not received. Can you please let me know the status?

I'm hoping this process will go away with the ACTIV portal now being publicly available for companies who have their therapeutic agents ready for submission. The sooner we can get OD to clear changes to the NIH portal and get feedback from you, Joe, and Mike on the ACTIV portal we can move this along — OCPL has already provided 2 separate buttons to direct folks on the ACTIV website.

Thanks,
Ashley

Begin forwarded message:

From: "Walsh, Elizabeth (NIH/OD) [E]" [b6]
Date: September 23, 2020 at 10:45:59 PM EDT
To: "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: Inquiry from Portal Submitter

Hi Ashley,

Tara received the attached email (attachment 1) from a person who submitted a candidate through the COVID-19 Candidate and Technologies Portal. I sent their information along to you/NCATS on 8/25 (attachment 2). I'm wondering if the ACTIV folks just weren't interested? Could you check?

Also, haven't forgotten about the portal language. Just a crazy week with lots of deadlines. I'll try to address by the end of the week.

Best,
Beth

Elizabeth R. Walsh, PhD
Health Science Policy Analyst
Immediate Office of the Director, NIH
A: Building 1, Room 108
P: [b6] | M: [b6]
--

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/7/2020 12:57:50 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV-2/-3 Trial Oversight Committee Meeting
Location: <https://fnih.zoom.us> b6
Start: 7/8/2020 7:00:00 PM
End: 7/8/2020 8:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/2/2020 5:04:48 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponeim]
Subject: FW: ACTIV EC Pre-call
Attachments: 10.7 ACTIV Executive Committee Meeting 20201002 v2draft.pptx; October 7 EC WG Co-chair Attendees as of 10-2.xlsx

FYI

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, October 2, 2020 12:15 PM
To: Melencio, Cheryl (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Margaret Anderson <marganderson@deloitte.com>; Chen, Helen Q. <qingchen@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; Hawk, Harrison <hhawk@deloitte.com>; Santos, Michael (FNIH) [T] [b6]; Stratton, Benjamin <bstratton@deloitte.com>; btolman <btolman@deloitte.com>; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Appell, Evan <eappell@deloitte.com>; Sorosa, Alex <asorosa@deloitte.com>; Connelly, Sarah <sconnelly@deloitte.com>
Cc: Wood, Gretchen (NIH/OD) [E] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; [b6]; Simon, Dina (NIH/OD) [C] [b6]
Subject: RE: ACTIV EC Pre-call

Please find materials attached for our AMP EC pre-call at 1PM

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/7/2020 12:56:30 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Trial Oversight Meeting for ACTIV 2/3

OK—thanks!

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, October 7, 2020 8:56 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Trial Oversight Meeting for ACTIV 2/3

Hi Ashley,

As this was not a subgroup to the working group, but an actual Governance Committee for the trial I assumed that it would be covered by the ICs and not OD, so I have not added you. I will do so now.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 8:53 AM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: Trial Oversight Meeting for ACTIV 2/3

Hi Stacey,

May I have the calendar invite to the Trial oversight meeting for ACTIV2/3 today? I'm not sure what's happened but I do not have many of the Clinical TX subgroup meetings on my calendar.

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/12/2020 7:09:13 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV Leadership Team Pre-call
Location: see webex below
Start: 12/14/2020 9:00:00 PM
End: 12/14/2020 9:30:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/7/2020 12:54:25 PM
To: Fritz, Craig (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79148d8c0cee49689fd637304bb82b42-fritzcm]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: Update on Forthcoming Rollouts

You're awesome – thanks!!

From: Fritz, Craig (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 8:54 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

A so checking on that!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 8:48 AM
To: Fritz, Craig (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

Thanks, Craig! If they have the updated ACTIV-5 release with the CT identifier that would be good too but not critical – preparing for FC's meeting with the Secretary w/ materials due tomorrow because of the Monday holiday.

Thanks again,
Ashley

From: Fritz, Craig (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 8:42 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

I will ask NIAID for their most current version.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, October 7, 2020 8:39 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Fritz, Craig (NIH/OD) [E] [b6]
Subject: RE: Update on Forthcoming Rollouts

Hi Renate and Craig,

Do we have the draft release for the ITAC trial?

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, October 6, 2020 5:05 PM

To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];
Parker, Ashley (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David
(FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T]
[b6]; McManus, Ayanna (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];
Wojtowicz, Emma (NIH/OD) [E] [b6]; Seigfreid, Kim (NIH/OD) [E] [b6];
Schwetz, Tara (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Hallett,
Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Brodd, Lauren
(NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T]
[b6]

Subject: Update on Forthcoming Rollouts

Good afternoon:

I wanted to provide an update on several forthcoming rollouts. As is always, this timing is tentative and subject to change. We'll keep you posted as we get more information.

Likely Oct. 7 or 8:

ITAC Hyperimmune Globulin (ACTIV-like)

Rollout:

- NIAID News Release
- Social Media
- Release is cleared

ACTIV-5 BET

Rollout:

- NIAID News Release only (no media telebriefing)
- Add to ACTIV Therapeutics page
- Release is cleared

Likely Thursday, October 15:

ACTIV-1 Immune Modulators

Rollout:

- Embargoed News Release
- Embargoed Media Advisory
- Release in clearance
- Embargoed Media Telebriefing (by phone only/no video)
 - Principals:
 - Francis Collins
 - Chris Austin
 - Paul Stoffels, Janssen
 - BMS spokesperson
 - AbbVie does not want to participate
 - Participants:
 - David Wholley
- Social media event

As early as October 19:

Novavax Phase 3 Vaccine

Rollout:

- Embargoed News Release
- Embargoed Media Advisory

- Embargoed Media Telebriefing (by telephone; no video)
 - Principals:
 - Francis Collins
 - Tony Fauci
 - Matt Hepburn
 - Novavax Spokesperson
- Social Media Event

December:

- Sanofi Phase 3 Vaccine Trial

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/28/2020 11:32:23 AM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: Re: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Thank you, Renate!
Ashley

On Sep 25, 2020, at 8:59 PM, Myles, Renate (NIH/OD) [E] [b6] wrote:

No problem, Ashley. We'll add it.

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
[b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, September 25, 2020 5:58 PM
To: Myles, Renate (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi Renate and Emma,

FNIH raised questions about including links on the ACTIV Tx page. I let them know we already have links to [CT.gov](https://www.clinicaltrials.gov) on the Therapeutics webpage and will add others when they are ready – Stacey will share this information with the Clinical Tx WG.

Whenever you have a chance, can we please add the link to "[Rise Above COVID](#)" under more information for ACTIV-2? We try to limit sending any ACTIV updates to once per week but I wanted to let you know before NIH and FNIH meets again on Monday morning. I completely understand OCPL has a ton of other things to manage!

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, September 25, 2020 5:17 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
[b6]
Cc: Brodd, Lauren (NIH/OD) [E]; [b6]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Thanks, Ashley,

This is great! Go with Rise Above COVID.

And thanks for letting me know where the clinicaltrials.gov links are. I bet the teams, as I were just not looking for it to be there.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, September 25, 2020 5:13 PM
To: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi Stacey,

The [CT.gov](https://www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials) links to the trials listed below (ACTIV-2,3, 4a, 4b) are already available on the Therapeutics page under more information – see “Clinical Trial Record” for each trial that has launched <https://www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials>.

We can add the link to the ACTIV-2 website under the ACTIV-2 trial – OK to list as Rise Above COVID Campaign? I’m also happy to work with OCPL to add additional links once they are ready.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, September 25, 2020 4:49 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi Ashley,

The team would like the ACTIV-2 website:
<https://www.activ-2.org/en>

They would like the [Clinicaltrials.gov](https://clinicaltrials.gov) links added:

ACTIV-1: TBD

ACTIV-2:

<https://clinicaltrials.gov/ct2/show/NCT04518410?term=ACTIV&cond=Covid19&draw=2&rank=3>

ACTIV-3:

<https://clinicaltrials.gov/ct2/show/NCT04501978?term=ACTIV&cond=Covid19&draw=2&rank=2>

ACTIV-4a:

<https://clinicaltrials.gov/ct2/show/NCT04505774?term=ACTIV&cond=Covid19&draw=2&rank=4>

ACTIV-4b:

<https://clinicaltrials.gov/ct2/show/NCT04498273?term=ACTIV&cond=Covid19&draw=2&rank=5>

ACTIV-4c: TBD

ACTIV-5: TBD

In addition, there will be ACTIV websites built for ACTIV-1 and possibly ACTIV-4 that will need to be added later.

The teams would like them added to the Therapeutics page where the trials and the press releases are listed.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Friday, September 25, 2020 8:52 AM

To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]

Cc: Brodd, Lauren (NIH/OD) [E] [b6]

Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Thanks, David for looping me in – happy to help.

Hi Stacey – can you please send me the specific changes and links that should be added to the [therapeutics page](#)? Also to be clear, these changes are preferred to the [therapeutics page](#) versus the [therapeutics clinical WG page](#)?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]

Sent: Friday, September 25, 2020 8:35 AM

To: Parker, Ashley (NIH/OD) [E] [b6]

Cc: Adam, Stacey (FNIH) [T] [b6]

Subject: FW: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Ashley, as promised here is the issue we need addressed with Renate. Thank you very much for taking this on. David

From: Adam, Stacey (FNIH) [T] [b6]

Sent: Thursday, September 24, 2020 5:55 PM

To: Wholley, David (FNIH) [T] [b6]

Subject: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi David,

Again on the ACTIV Cross Trial Operations call, it was raised by the teams if we can get the specific trial website links put up on the main ACTIV Therapeutics webpage? Shall we follow up with NIH OD Comms team again to see if there was a ruling on this?

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct. [b6] Mobile [b6]

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

<image001.jpg> <image002.jpg> <image003.jpg> <image004.jpg>

Donate to the FNHI's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

<image005.png>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/12/2020 5:11:26 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV Leadership Team Meeting #11

Location: <https://fnih.zoom.us/j/91812121212> **b6**

Start: 12/16/2020 3:00:00 PM

End: 12/16/2020 4:00:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/6/2020 6:34:25 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: Accepted: ACTIV Vaccines Working Group meeting
Location: <https://fnih.zoom.us> b6
Start: 11/11/2020 6:00:00 PM
End: 11/11/2020 7:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/15/2020 5:11:28 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV Leadership Call #9

Location: <https://fnih.zoom.us> b6

Start: 10/21/2020 1:15:00 PM

End: 10/21/2020 2:15:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 11/3/2020 7:59:34 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Wohl, David A [b6]
Subject: RE: Contact for UNC Site for ACTIV-2

Thanks so much, Stacey!

Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Tuesday, November 3, 2020 2:58 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wohl, David A [b6]
Subject: Contact for UNC Site for ACTIV-2

Hi Ashley,

ACTIV-2 is open and enrolling at UNC. Dr. David Wohl, the site PI there, has asked if you can call him to discuss. His number is [b6] I have also cc'd him on this email if that is easier.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] Mobile: [b6]
fnn.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnni.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/22/2020 12:38:45 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]
Subject: RE: Confirmation of ACTIV-4c and ACTIV-5 launch

Thanks, Stacey – greatly appreciate the quick response.
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, September 21, 2020 8:37 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Chen, Helen Q. <qingchen@deloitte.com>
Subject: RE: Confirmation of ACTIV-4c and ACTIV-5 launch

Hi Ashley,

I am still waiting on response about ACTIV-4c, but I just heard from ACTIV-5 that FDA has not responded yet, so it will likely be the week of 9/28 instead. I will let you know as soon as I hear on the other.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, September 21, 2020 8:28 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: Confirmation of ACTIV-4c and ACTIV-5 launch

Hi Stacey,

Dr. Collins has his meeting with the Secretary on Wednesday and we have the bullet below on the agenda. FC asked me to confirm if the launch of ACTIV-4c and ACTIV-5 are on schedule to launch this week before we send materials to HHS.

- Projected launch of ACTIV-4 post-hospitalized and ACTIV-5 phase 2 inpatient trial, week of Sept. 21

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 11/7/2020 10:11:06 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Hall, Matthew (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c76a7b2623714aaaa095fda97973f5e6-hallma_b4f6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: FW: Requested Implementation Plan for Recommendations from SARS-CoV-2 Antiviral Therapeutics Summit
Attachments: 20201106 - Virus War -- Counter-Attack Plan for the U.S. Government.pdf

Importance: High

FYI. If interested, please contact him directly.

FC

From: John Gregg [REDACTED] b6
Sent: Saturday, November 7, 2020 12:43 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Subject: Requested Implementation Plan for Recommendations from SARS-CoV-2 Antiviral Therapeutics Summit
Importance: High

Dear Dr. Collins:

Thank you for sponsoring and addressing Friday afternoon's NIH SARS-CoV-2 Antiviral Therapeutics Summit. At its conclusion you provided your email address and asked for specific recommendation on how to implement the suggestions and recommendations of the members of the expert panels. As a veteran antiviral drug developer for both the biggest drug companies in the world (Pfizer, Novartis, J&J, BMS), as well as start-up biopharmaceutical companies developing SARS-CoV-2 direct antivirals, interacting with all of the relevant federal agencies, I offer the well thought out 29 page detailed implementation plan (with executive summary) for the suggestions made in the Summit that are attached on this email.

The key recommendations are for:

[REDACTED] b4

b4

I would like to work with you as an advisor on implementing this plan. You can call me any time (day, night, weekends, etc.). I don't mind. This is of paramount importance.

FYI, I am working on two very different repurposed SARS-CoV-2 antiviral repurposed clinical stage compound compounds that meet all of the criteria of the ideal Target Product Profile discussed in the Summit today and would welcome any support from NIH. I have had BARDA Tech Watch Meetings and Interactions with DMID PCS, FDA, CDC, VA, DOD, etc. As a result, I have the experience of a "user" of the system and have previously gotten anti-infective drugs approved under priority review in record time in both the big pharma and small biotech settings.

For 10 years, I was in charge of planning for Pfizer's old coronavirus/picorna virus programs focusing on the 3C and 3CL proteases. After that, I worked with my companies and DMID PCS on screening new mechanism repurposed compounds for SARS, MERS, and SARS-CoV-2. We started developing drugs with the identified profile starting the week in January before the ASM Biothreat Meeting for medical countermeasures in response to respiratory pandemic pathogens. I believe the right drugs can be rapidly developed to augment Veklury (Remdesivir), the one antiviral drug currently approved. There should be many approved by now and this must be fixed.

Thanks again for a great meeting.

Sincerely,

John Gregg

John M.H. Gregg, MBA, CLP
President, CEO
BalinBac Therapeutics, Inc.
657 Rosedale Road
Princeton, New Jersey 08540
Phone: **b6**
Mobile: **b6**
Email: **b6**
Web: www.balinbac.com
Linked-In: <https://www.linkedin.com/in/john-gregg-2b61b83/>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/15/2020 12:23:15 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV Cross Trial Meeting
Location: <https://fnih.zoom.us> b6
Start: 11/20/2020 1:30:00 PM
End: 11/20/2020 3:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/30/2020 7:31:21 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponeim]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

OK.

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 3:30 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

I think it can wait for the next update, since OWS is at least listed as a leadership organization (unlike on the FNIH site that doesn't have it anywhere).

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 3:21 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

I have no preference here – either is fine.

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 2:56 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Ok. Maybe we can send to Renate/Emma next time we send edits, unless you think it should be done sooner?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 2:19 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Yes. I noticed this as well – the language was drafted before OWS was established but we should probably update and include, similar to how we updated the portal language.

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 2:01 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Ok I will update and send to Cheryl as an FYI and CC you.

Just another note, I was on the FNIH website (<https://fnih.org/what-we-do/programs/activ-partnership>) to copy how they listed Rhythm, and unless I'm missing it, I don't see OWS listed in the opening text or on the list of leadership organizations. Maybe there is a reason for that, but wanted to flag.

And on a similar note, I double checked the ACTIV website and OWS is listed in the leadership organizations, but should it also now be mentioned in the opening text?

Coordinated by the Foundation for the National Institutes of Health (FNIH), ACTIV brings NIH together with its sibling agencies in the Department of Health and Human Services, including the Biomedical Advanced Research and Development Authority (BARDA), Centers for Disease Control and Prevention (CDC), and the U.S. Food and Drug Administration (FDA); other government agencies including the Department of Defense (DOD) and Department of Veterans Affairs (VA); the European Medicines Agency (EMA); and representatives from academia, philanthropic organizations, and numerous biopharmaceutical companies.

<https://www.nih.gov/research-training/medical-research-initiatives/activ>

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 1:31 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Fine to delete from WG and master. We have old version to refer to if needed.

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 1:29 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

For Frank S., should I just delete him entirely? Or delete him from the WG and master lists but create a new "inactive" tab and add him there....wasn't sure if we would need his info in the future for any reason?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 1:17 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Thanks!! We'll also need to send the revised excel sheet to Cheryl as FYI once updated.

Thanks!
Ashley

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 1:14 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Thanks for sharing. And yes I will update the excel sheet. I have a few other things I need to do first, but I'll also double check that the WG website pages are consistent with the attached updated slides (like if anything should now have a check mark for completion, etc.).

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 12:51 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]
Brodd, Lauren (NIH/OD) [E] [b6]
Subject: FW: ACTIV Briefing slides updated 9-30-20.pptx

Hi all,

Per David's note below: KSQ Therapeutics is no longer an ACTIV industry partner and should be replaced with Rhythm Therapeutics on our list of industry partners on the website. David must have already notified the FNIH COMMs team as the change was updated at some point today on their site <https://fnih.org/what-we-do/programs/activ-partnership>.

Apparently, Frank Stegmeier listed on the preclinical WG roster for KSQ Tx is no longer a participant – not sure if we should remove his name from the public preclinical list or keep it since he was on the group at some point? Renate and Emma, I defer to your preference.

Lauren – can you please remove Frank S. from our preclinical roster on the excel sheet?

Including FNIH's updated ACTIV slides as FYI only.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, September 30, 2020 12:16 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Gonzalez, Nina <niningonzalez@deloitte.com>; Appell, Evan <eappell@deloitte.com>; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Please see my answers to your questions below, in italics. Revised set attached. Thanks for your close read, Ashley!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 9:50 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Hi David,

Looks great! Please see comments attached and below.

- Slide 3 – replaced KSQ Tx with Rhythm (do we need to do the same on the ACTIV and FNIH websites?). The preclinical WG has a rep from KSQ Tx although David Meeker has moved to Rhythm (20 or 21 industry partners?) – *not sure how this happened, but Deloitte and I had discussed making this same change and when I double-checked the version I sent Francis and the group last night, it showed only Rhythm, not KSQ. The KSQ rep*

on the Preclinical WG is no longer there and did not contribute much, so we should remove KSQ from the lists and indeed update both the NIH and FNIH websites.

- Slide 3 – add FNIH to non-profit section or move logo on the far left to the non-profit section? I believe your comment says FNIH is listed on the NIH website in this way, so yes, I've listed NIH and boosted the number of non-profits to 4.
- Slide 7 – missing ACTIV data and inventory efforts (arrow) – that's deliberate. That effort pretty much wound up in June and has been subsumed into the NCATS and other databases. No need to include it.
- Slide 12 – is ACTIV-5 still projected to launch this week? I checked with John Beigel, and they are still waiting to get their final safe to proceed from FDA. They are expecting this Friday, but next week (Oct. 5) is the new "projected" date. I have made the change.
- Slide 13 – agree with Francis - yes, this slide is gone
- Slides 14-16 – mention the CTC WG has completed all activities on one of these slides or just say verbally? – just say verbally. The three checkmarks tell the tale.
- Slide 18 – Current language on the slide is fine but the NIH portal language is in the process of being revised. Interested parties should submit diagnostics, vaccines, technologies, or other information for awareness of NIH. All preclinical and clinical therapeutics will be routed to the ACTIV portal. – I corrected the language by replacing what was on the slide with your second sentence here.

Thanks and good luck tomorrow.

Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, September 29, 2020 11:21 PM
To: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Looks like a definite upgrade! Lots of good stuff here. But I have concerns about Klick and slide 13, that needs to go.

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, September 29, 2020 9:00 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: ACTIV Briefing slides updated 9-30-20.pptx

A refreshed, redesigned high level ACTIV PowerPoint deck for you all. You can share any thoughts by email, or in war room tomorrow, if you'd like.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/15/2020 12:22:39 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]

Subject: Accepted: ACTIV Cross Trial Meeting

Location: <https://fnih.zoom.us/j/91812121212> **b6**

Start: 12/18/2020 1:30:00 PM

End: 12/18/2020 3:00:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/21/2020 12:24:01 AM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponeIm]
Subject: Re: RESPONSE REQUESTED: Permission to list to you on ACTIV Website

Thanks!!

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [REDACTED]

On Sep 19, 2020, at 6:49 PM, Melencio, Cheryl (FNIH) [T] [REDACTED] wrote:

Response from Sheri Hild.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[REDACTED]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

<image001.png>

From: Hild, Sheri (NIH/OD) [E] [REDACTED]
Sent: Friday, September 18, 2020 8:45 PM
To: Melencio, Cheryl (FNIH) [T] [REDACTED]
Subject: Re: RESPONSE REQUESTED: Permission to list to you on ACTIV Website

Yes you can list me and the information is correct. Sheri

Sent from my iPhone

On Sep 18, 2020, at 9:21 AM, Melencio, Cheryl (FNIH) [T] [REDACTED] wrote:

Dear Dr. Hild:

NIH has an ACTIV webpage. They would like to update it to include you on the Therapeutics – Pre-clinical Working Group listing. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please let me know if we have your permission to list you on the NIH website.**

Please confirm if this listing is correct:

Sheri Hild, Ph.D.

Program Director for National Primate Research Centers

Office of Research and Infrastructure Program, NIH

Thank you.

Cheryl

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19:

fnih.org/pandemic

<image001.png>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/2/2020 12:33:29 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]

Subject: Accepted: ACTIV Cross Trial Meeting

Location: <https://fnih.zoom.us/j/91812121212> **b6**

Start: 8/28/2020 12:30:00 PM

End: 8/28/2020 2:00:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/29/2020 10:47:57 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Question?

Thanks, Stacey!

Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Tuesday, September 29, 2020 6:47 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Question?

Hi Ashley,

I will preface that I do not know the answer, but I think you are correct that it is day 1 = 1 injection and day 22 = 1 injection.

Thanks,
STacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, September 29, 2020 6:41 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: Question?

Hi Stacey,

Can you help me with something (I know Mike is the vaccines POC but thought you may know)? For the Sanofi vaccine trial the dose for one group is listed as "2 injections of SARS-CoV-2 vaccine formulation 1 with adjuvant 1 at Day 1 and Day 22?" <https://clinicaltrials.gov/ct2/show/study/NCT04537208>

Does this really mean one injection on day 1 and 1 injection on day 22? I can't imagine 2 injections on day 1 and 2 injections on day 22 although it reads this way.

Thanks,
Ashley

Ashley Parker, Ph.D.

Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

Office of the Director | National Institutes of Health

APAR0000021587

Tel: [redacted] b6



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 11/18/2020 4:56:28 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6] [b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6] Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]

Subject: ACTIV-2/-3 Trial Oversight Committee Meeting

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201117.pdf

Location: <https://fnih.zoom.us/j/91811111111> **b6**

Start: 11/18/2020 8:00:00 PM

End: 11/18/2020 9:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; **b6**; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Harrigan, Rachel (HHS/IOS); Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhan, Mina

Dear ACTIV-2/-3 TOC Members,

Please find attached the slides for today's meeting.

Thanks,
Stacey

Join Zoom Meeting
<https://fnih.zoom.us/j/91811111111> **b6**

Meeting ID: **b6**

Password: **b6**

One tap mobile

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US (San Jose)
US (Tacoma)

Meeting ID: **b6**

Password: **b6**

Find your local number: <https://fnih.zoom.us/j/91811111111> **b6**

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/15/2020 12:04:10 AM
To: Jens Lundgren [b6]; Jim Neaton [b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Birgit Grund [b6]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; David Douglas [b6]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hochman, Judith [b6]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; [b6]; Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; LaVange, Lisa M [b6]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; [b6]; [b6] Leifer, Eric (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82f6ef6b63654d1294890664f81c9c95-leifere]; [b6] Scott Berry [b6] Wright, Clinton (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e18bd48748f4d7dab41338948aa9a59-wrightclb]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=febabc96e8d04b5fa51d5749ad0c74a6-David.Dougl]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; [b6]; [b6] Thomas Stock [b6]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc];
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Philip, Ritika [b6] Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Marks, Gilbert

b6

US (San Jose)
US (San Jose)

Meeting ID: **b6**

Passcode: **b6**

Find your local number: <https://fnih.zoom.us>

b6

Sent: 11/19/2020 6:05:06 PM
To: Espinoza, Tasha (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c590ff12ed4d4cc087e2d4ab3f91a437-espinozata]
Subject: RE: Operation Warp Speed Funding Request

Hi Tasha,

I would have to ask Dr. Tabak and/or Tara about funding for FNIH/ACTIV program mana

From: Espinoza, Tasha (NIH/OD) [E] [b6]
Sent: Thursday, November 19, 2020 12:55 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Operation Warp Speed Funding Request

Hi Ashley,

Greetings from OB! Reaching out in case you can point me in the right direction again. There is request in for OWS funding for FNIH ACTIV Program Management. We last connected in July about the funding request. Just looking for a POC.

Thank you,
Tasha

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 13, 2020 2:47 PM
To: Espinoza, Tasha (NIH/OD) [E] [b6]
Cc: Mazzucco, Anna (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: RE: Operation Warp Speed Update for Tomorrow (7/14)

Hi Tasha,

Anna – I've dropped David off of the thread for NIH internal discussion.

Attached is the budget request we submitted to OWS for ACTIV therapeutic trials but this is independent of the funds needed for project management support by FNIH.

I've confirmed with Dr. Tabak –we have used OT from the OD to fund FNIH thus far and support Deloitte project management. The additional request for FNIH is critical. We have run out of resources and need them replenished; Please see the low-high estimates below \$7.1M-10M:

ACTIV management via FNIH	\$M	7.1	10
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Thank you,
Ashley

From: Mazzucco, Anna (NIH/OD) [E] [b6]
Sent: Monday, July 13, 2020 1:03 PM
To: Espinoza, Tasha (NIH/OD) [E] [b6]

Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 > Wholley, David (FNIH) [T] <[REDACTED] b6 >
Subject: Re: Operation Warp Speed Update for Tomorrow (7/14)

Ah ok, that's helpful context and sounds different from the program management support I am familiar with through Tara's office. Perhaps Ashley can help fill in some additional details- looping in also David Wholley at FNIH who can provide details on timing.

Very Sincerely,

Anna

From: "Espinoza, Tasha (NIH/OD) [E]" <[REDACTED] b6 >
Date: Monday, July 13, 2020 at 12:56 PM
To: "Mazzucco, Anna (NIH/OD) [E]" <[REDACTED] b6 >
Cc: "Parker, Ashley (NIH/OD) [E]" <[REDACTED] b6 >
Subject: RE: Operation Warp Speed Update for Tomorrow (7/14)

Hi Anna,

Thanks so much for your help. My contact on the OWS team told me this was related to ACTIV monoclonal antibodies activity for NIH/OD. They mentioned that they were working with an estimate of \$2.5M. A lot of what these meetings I've been attending are to help coordinate the budget estimates and timing of when the funding is needed, so that's the type of information I am looking for. This information is helpful to the OWS team so they can ensure that the funding gets to the agencies when it's needed for obligation.

Thanks!
Tasha

From: Mazzucco, Anna (NIH/OD) [E] <[REDACTED] b6 >
Sent: Monday, July 13, 2020 11:12 AM
To: Gladman, Jordan (NIH/OD) [E] <[REDACTED] b6 >; Espinoza, Tasha (NIH/OD) [E] <[REDACTED] b6 >
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Subject: Re: Operation Warp Speed Update for Tomorrow (7/14)

Sure- happy to help try to clarify/track this down.
OD funds are being used to support program management for the cross-cutting trans-NIH COVID-19 related projects, including ACTIV and FNIH's involvement there. I am looping in Pat because she may have more specifics on the exact request if helpful!

Very Sincerely,

Anna

From: "Gladman, Jordan (NIH/OD) [E]" <[REDACTED] b6 >
Date: Monday, July 13, 2020 at 11:07 AM
To: "Espinoza, Tasha (NIH/OD) [E]" <[REDACTED] b6 >
Cc: "Mazzucco, Anna (NIH/OD) [E]" <[REDACTED] b6 >, "Parker, Ashley (NIH/OD) [E]" <[REDACTED] b6 >
Subject: RE: Operation Warp Speed Update for Tomorrow (7/14)

Tasha,

I suspect Anna Mazzucco and/or Ashly Parker (cc'ed) would be the people most likely to know about FNIH Program Management Support. Anna has been working with Tara with the Program Management side of ACTIV/COVID efforts and Ashley is the superstar helping NIH and FNIH coordinate ACTIV. Do either of you have any insight into the request? Anna and Ashley Tasha is now the point person working to coordinate the OWS and NIH COVID budget process so leadership can understand where our money is allocated and going.

Best,

Jordan

From: Espinoza, Tasha (NIH/OD) [E] [b6]
Sent: Monday, July 13, 2020 10:58 AM
To: Gladman, Jordan (NIH/OD) [E] [b6]
Subject: Operation Warp Speed Update for Tomorrow (7/14)

Good morning!

Hope you had a great weekend.

In prepping for the OWS Therapeutics meeting tomorrow, I wanted to reach out to see if you knew anything about an OD request for Program Management for FNIH. It came up at a meeting last week and would like to track down more information. I reached out to the Budget Officer and there has been funding already obligated, but it sounds like this is a new request.

Thanks,
Tasha

Tasha Espinoza
National Institutes of Health, Office of Budget
Building 1, Room B1-18A

[b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 11/30/2020 1:32:25 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]

Subject: Canceled: ACTIV Call "War Room"

Location: Dial-in: [b6] Passcode: [b6]

Start: 12/4/2020 1:00:00 PM

End: 12/4/2020 1:30:00 PM

Show Time As: Free

Recurrence: Weekly
every Friday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Lane, Cliff (NIH/NIAID) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]

Due to conflict cancelling December 4 - 8 a.m. War Room call

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 11/11/2020 10:41:19 PM
To: Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]

Subject: Canceled: ACTIV Preclinical - In Vivo Strategy

Location: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

Start: 11/20/2020 3:00:00 PM

End: 11/20/2020 4:00:00 PM

Show Time As: Free

Recurrence: (none)

Hi all,

I'm cancelling this occurrence due to scheduling conflicts with group members.

Thanks,
Harrison

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/28/2020 4:03:06 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]
Subject: ACTIV-2/-3 Trial Oversight Committee Meeting
Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201028.pdf
Location: https://fnih.zoom.us/j/[b6]

Start: 10/28/2020 7:00:00 PM
End: 10/28/2020 8:00:00 PM
Show Time As: Tentative

Recurrence: Weekly

every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert

(OS/ASPR/BARDA) (CTR); Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS)

Dear ACTIV-2/-3 TOC Members,

Please see attached the slides for today's call.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/14/2020 10:02:33 PM
To: Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmore]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Thomas Stock [b6]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; David Douglas [b6]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=febabc96e8d04b5fa51d5749ad0c74a6-David.Dougl]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika [b6]; Lawlor, Ciarán [b6]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholley]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; VND Shreeve, Chris [b6]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastrop]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kuethe, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; Sorosa, Alex David [asorosa@deloitte.com]
Subject: Canceled: ACTIV Cross Trial Operations Strategy/Problem Solving Meeting
Location: https://fnih.zoom.us/j/[b6]

Start: 11/26/2020 2:00:00 PM
End: 11/26/2020 3:00:00 PM
Show Time As: Free

Recurrence: Weekly

every Thursday from 9:00 AM to 10:00 AM

Required Attendees:	Bugin, Kevin (FDA/CDER); Kim, Peter (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E]; Atkinson, Jane (NIH/NCATS) [E]; Patterson, Amy (NIH/NHLBI) [E]; Beigel, John (NIH) [E]; Dunsmore, Sarah (NIH/NCATS) [E]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Thomas Stock; Erhardt, William (HHS/IOS); Harrigan, Rachel (HHS/IOS); David Douglas; Douglas, David (HHS/IOS); Stock, Thomas (HHS/IOS)
Optional Attendees:	Knox, Shamay (NIH/NIAID) [E]; Parker, CAPT Sheri (HHS/IOS); Philip, Ritika; Lawlor, Ciarán; Chen, Helen Q.; Appell, Evan; Wholley, David (FNIH) [T]; Punturieri, Antonello (NIH/NHLBI) [E]; Boucher, Cynthia (NIH/NCATS) [E]; Teyhen, Deydre (HHS/IOS); Higgs, Elizabeth (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; VND Shreeve, Chris; Decastro, Philip (NIH/NIAID) [E]; Illanes, Christine (NIH/NIAID) [E]; Ramakrishnan, Raahul; Kuethe, Christine (OS/ASPR/BARDA) (CTR); Sorosa, Alex David

Dear NIH Trial Operational Representatives,

Cancelling this last Thursday in November due to Thanksgiving!

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/9/2020 6:44:58 PM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eada7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6]
[b6]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]
Subject: ACTIV-2/-3 Trial Oversight Committee Meeting
Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201209.pdf

Location. <https://fnih.zoom.us/j/91811111111> b6

Start: 12/9/2020 8:00:00 PM

End: 12/9/2020 9:00:00 PM

Show Time As. Tentative

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Higgs, Elizabeth (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; b6 Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Dear ACTIV-2/-3 TOC Members,

Please find attached the slides for today's meeting.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/23/2020 1:48:35 PM
To: Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6]
[b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen; [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Kelly Beazley [b6]
[b6]

Subject: ACTIV-2/-3 Trial Oversight Committee Meeting
Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201023.pdf

Location: <https://fnih.zoom.us/j/> **b6**

Start: 10/23/2020 2:00:00 PM

End: 10/23/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Woodcock, Janet (FDA/CDER); Wholley, David (FNIH) [T]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; **b6**; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Kelly Beazley

Dear ACTIV-2/-3 TOC Members,

Please find attached the slides for today's call.

Thanks,
Stacey

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 11/2/2020 3:55:03 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse [jmendelson@deloitte.com]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
Subject: ACTIV EC & WG Co-chair Pre-call
Location: see webex below
Start: 11/2/2020 9:45:00 PM
End: 11/2/2020 10:15:00 PM
Show Time As: Tentative

Required Attendees: Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adam, Stacey (FNIH) [T];

Alvarez, Rosa; Anderson, Margaret; Appell, Evan; Chen, Helen; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Santos, Michael (FNIH) [T]; Stratton, Ben, Tolman, Brett; Tountas, Karen (FNIH) [T], Wachtel, Jonathan, Sorosa, Alex, Connelly, Sarah

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

Dr. Collins has a conflict at 4:15 rescheduling to 4:45 p.m.

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 11/30/2020 1:11:04 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]

Subject: ACTIV Call "War Room"

Location: Dial-in: Passcode:

Start: 12/4/2020 1:00:00 PM

End: 12/4/2020 1:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Friday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David, Collins, Francis (NIH/OD) [E], Tabak, Lawrence (NIH/OD) [E], Parker, Ashley (NIH/OD) [E], Anderson, James (NIH/OD) [E], Austin, Christopher (NIH/NCATS) [E], Lane, Cliff (NIH/NIAID) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]

Extending to end of December

Dial-in:

Passcode:

Dr. Tabak as Leader:

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 11/5/2020 5:00:05 AM
To: Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bfdfccfda71ced-jatkinso]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmores]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Thomas Stock [b6]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; David Douglas [b6]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=febabc96e8d04b5fa51d5749ad0c74a6-David.Dougl]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika [b6]; Lawlor, Ciarán [b6]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Puntuneri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris [b6]; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kuethe, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]

b6

US (Houston)
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United Kingdom

Meeting ID: **b6**

Passcode: **b6**

Find your local number: <https://fnih.zoom>. **b6**

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 11/30/2020 1:07:34 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: ACTIV Call "War Room"

Location: Dial-in: [b6]; Passcode: [b6]

Start: 12/2/2020 1:00:00 PM

End: 12/2/2020 1:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David, Collins, Francis (NIH/OD) [E], Tabak, Lawrence (NIH/OD) [E], Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]

Optional Attendees: McManus, Ayanna (NIH/OD) [E], Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Carver, Trea (NIH) [C]; Lagos, Enrique (NIH/NCATS) [E]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]

Extending to end of December

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: 6397270#

From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 11/6/2020 2:27:42 PM
To: Young, John [john.young.jy3@roche.com], Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6]; [b6] USARMY MEDCOM USAMRIID (USA) [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6] Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]

Subject: Canceled: ACTIV Preclinical - In Vivo Strategy

Location: <https://deloitte.zoom.us/j/92561234567> [b6]

Start: 11/6/2020 3:00:00 PM

End: 11/6/2020 4:00:00 PM

Show Time As: Free

Recurrence: (none)

Hi all,

Cancelling this meeting due multiple scheduling conflicts. Apologies for the late notice.

Best,
Harrison

Join Meeting

Password:

Phone one-tap:

b6

Join by Telephone

Dial:

b6

Meeting ID:

b6

Password:

International numbers

Zoom technology includes options for recording a meeting. If a meeting is being recorded, an audio and/or visual warning will be provided when you join a recorded meeting. A warning will also be provided if recording commences after you have joined the meeting. If you continue to participate in the meeting following these warnings, your participation will serve as your express consent to such recording.

This message (including any attachments) contains confidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and any disclosure, copying, or distribution of this message, or the taking of any action based on it, by you is strictly prohibited.

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v.E.1

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 11/30/2020 1:04:34 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: ACTIV Call "War Room"

Location: Dial-in: [b6] Passcode: [b6]

Start: 12/7/2020 1:00:00 PM

End: 12/7/2020 1:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Monday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David, Collins, Francis (NIH/OD) [E], Tabak, Lawrence (NIH/OD) [E], Austin, Christopher (NIH/NCATS) [E],

Anderson, James (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E], Lane, Cliff (NIH/NIAID) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina

(NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Carver, Trea (NIH) [C]; Sepulveda, Dorina (FNIH) [T]

Extending to end of December

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 12/11/2020 7:32:56 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: ACTIV Call "War Room"

Location: Dial-in: [b6] Passcode: [b6]

Start: 12/7/2020 1:00:00 PM

End: 12/7/2020 1:30:00 PM

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Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Carver, Trea (NIH) [C]; Sepulveda, Dorina (FNIH) [T]

Extending to end of December

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 12/11/2020 7:31:34 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen Q. [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Connelly, Sarah [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse [E] [jmendelson@deloitte.com]; Nasr, Hana [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Sorosa, Alex David [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Stratton, Benjamin [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [E] [jwachtel@deloitte.com]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]
Subject: January ACTIV Pre-call
Location: see webex below
Start: 1/19/2021 6:30:00 PM
End: 1/19/2021 7:00:00 PM
Show Time As: Tentative

Required Attendees: Wholley, David; Menetski, Joseph; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Santos, Michael (FNIH) [T]; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 11/9/2020 4:34:57 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Subject: Canceled: Daily ACTIV Call

Location: Dial-in: [b6] Passcode: [b6]

Start: 11/11/2020 1:00:00 PM

End: 11/11/2020 1:30:00 PM

Show Time As: Free

Recurrence: Weekly
every Wednesday from 8:00 AM to 8:30 AM

Required Attendees: Wholley, David (FNIH) [T], Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E];

Optional Attendees: Lane, Cliff (NIH/NIAID) [E], Austin, Christopher (NIH/NCATS) [E], Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C], Carver, Trea (NIH) [C];

Optional Attendees: Lagos, Enrique (NIH/NCATS) [E], Hughes, Karen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]

Cancelling meeting Wednesday, November 11 due to Veteran's Day Holiday.

Dial-in: [b6]

Passcode: [b6]

Dr. Tabak as Leader: [b6]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 9/25/2020 4:57:18 PM
To: Tajalli, Ada (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]
Subject: ACTIV EC & Working Group Co-Chair Meeting
Location: <https://fnih.zoom.us> b6

Start: 11/4/2020 3:00:00 PM
End: 11/4/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John
Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Appell, Evan; Chen, Helen; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Freire, Maria (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolnetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Sent: 9/28/2020 9:06:18 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: RE: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

Hi David,

I understand the draft ACTIV-2 letter is congratulating the sites for enrolling their first patient but how is the ACTIV-3 letter

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, September 28, 2020 1:38 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]
Subject: FW: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

Hi Francis:

Please see attached for your review and approval. Copying Ashley. Please let me know what else you might need from us. Thanks very much for your help.

David

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, September 28, 2020 1:27 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

Hi David,

Please find attached the DRAFT Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3 for review by NIH OD and FC. The idea would be that these drafts would be populated by the study teams and sent on behalf of FC and JW.

Would you mind passing these along, or should I work with Ashley Parker?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] Mobile: [b6]
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNHI's Pandemic Response Fund to combat COVID-19: fnhi.org/pandemic



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/8/2020 11:04:25 PM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmores]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Thomas Stock [b6]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; David Douglas [b6]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2e6786ea794ac5b4a257ddd9d738d2-David.Dougl]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika [b6]; Lawlor, Ciarán [b6]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris [b6]; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kueth, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Waring, Lorraine

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/19/2020 6:33:35 PM
To: Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bfdccfda71ced-jatkinso]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmore]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Thomas Stock [b6]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; David Douglas [b6]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=febabc96e8d04b5fa51d5749ad0c74a6-David.Dougl]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika [b6]; Lawlor, Ciarán [b6]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Puntuneri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-puntuneria]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris [b6]; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kuethe, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]
Subject: Canceled: ACTIV Cross Trial Operations Strategy/Problem Solving Meeting
Location: [https://fnih.zoom.us/j/\[b6\]](https://fnih.zoom.us/j/[b6])

Recurrence: Weekly
every Thursday from 9:00 AM to 10:00 AM

Required Attendees: Bugin, Kevin (FDA/CDER); Kim, Peter (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E]; Atkinson, Jane (NIH/NCATS) [E]; Patterson, Amy (NIH/NHLBI) [E]; Beigel, John (NIH) [E]; Dunsmore, Sarah (NIH/NCATS) [E]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Thomas Stock; Erhardt, William (HHS/IOS); Harrigan, Rachel (HHS/IOS); David Douglas; Douglas, David (HHS/IOS); Stock, Thomas (HHS/IOS)

Optional Attendees: Parker, CAPT Sheri (HHS/IOS); Philip, Ritika; Lawlor, Ciarán; Chen, Helen Q.; Appell, Evan; Wholley, David (FNIH) [T]; Puntuneri, Antonello (NIH/NHLBI) [E]; Boucher, Cynthia (NIH/NCATS) [E]; Teyhen, Deydre (HHS/IOS); Higgs, Elizabeth (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; VND Shreeve, Chris; Knox, Shamay (NIH/NIAID) [E]; Decastro, Philip (NIH/NIAID) [E]; Illanes, Christine (NIH/NIAID) [E]; Ramakrishnan, Raahul; Kuethe, Christine (OS/ASPR/BARDA) (CTR); Sorosa, Alex David

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/7/2020 6:44:32 PM
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[b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Kelly Beazley; [b6] Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6] Lisbeth Jørgensen [b6] Rose Li Central Account [FNIH@rosellassociates.com]; Dana Carluccio [b6] Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [asorosa@deloitte.com]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]
Subject: ACTIV-2/-3 Trial Oversight Committee Meeting
Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201007.pdf; Lilly BLAZE Combo Data 10072020.pdf
Location: https://fnih.zoom.us/j/[b6]

Start: 10/7/2020 7:00:00 PM
End: 10/7/2020 8:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Kelly Beazley; Harrigan, Rachel (HHS/IOS); Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina

Dear ACTIV-2/-3 TOC Members,

Please find attached the slides for our meeting today and the slides from the Lilly press conference earlier today for everyone's reference as well, since we will be discussing.

Thanks,
Stacey

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[b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Joe Eron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0be0452de96e48b7bc0cbcbf5b8d961c-joseph_eron]; Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]

Subject: Converting to Ad Hoc: ACTIV-2/-3 Trial Oversight Committee Meeting

Location: <https://fnih.zoom.us/j/6666666666>

Start: 11/25/2020 8:00:00 PM

End: 11/25/2020 9:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; 6666666666; Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Joe Eron; Michael Hughes

Dear ACTIV-2/-3 TOC Members,

We are converting next week's TOC meeting to an "Ad Hoc" meeting to allow for additional members of the ACTIV-2 team to join for the Analysis discussion.

Thanks,
Stacey

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From: Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]
Sent: 11/18/2020 7:57:44 PM
To: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: FW: Tomorrow's call

FYI

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, November 18, 2020 2:56 PM
To: Collins, Francis (NIH/OD) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E] [b6]
Subject: Tomorrow's call

Hi Francis.

We have our quarterly meeting scheduled for tomorrow at 11am, right before the ACTIV Leadership call. There are a couple of items that I'd like to flag for you (non-COVID), some updates and the 3Q 2020 FNIH Project Summaries.

The updates and the Summaries I will send electronically for your perusal. The items to flag are easier done on the phone. They are not super urgent.

Please let me know, given the million things on your schedule, if you want to keep the call tomorrow or find another time. Either way works for me.

Best, M.

From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 9/24/2020 1:34:19 PM
To: [b6] Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto, Gregory; [b6] Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]
CC: Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6]
Subject: ACTIV Preclinical - Data Portal Implementation
Location: <https://deloitte.zoom.us> [b6]
Start: 5/21/2020 1:00:00 PM
End: 5/21/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Join Meeting

Password:

Phone one-tap:

b6

Join by Telephone

Dial:

Meeting ID:

Password:

International numbers

b6

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v.E.1

Sent: 10/6/2020 4:14:50 PM
To: Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]
CC: Deacy, Mariam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=323067d2242245b380c486b4c8f990a4-deacyma]
Subject: RE: for your consideration: suggested edits to REDCap portal

Sorry for the multiple emails – the NIH OD portal is already updated

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, October 6, 2020 12:09 PM
To: Cutillo, Christine (NIH/NCATS) [E] [b6]
Cc: Deacy, Mariam (NIH/NCATS) [E] [b6]
Subject: RE: for your consideration: suggested edits to REDCap portal

Hi Christine,

Thanks so much! This should be fine – I will alert the team.

Thanks again,
Ashley

From: Cutillo, Christine (NIH/NCATS) [E] [b6]
Sent: Tuesday, October 6, 2020 12:07 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Deacy, Mariam (NIH/NCATS) [E] [b6]
Subject: RE: for your consideration: suggested edits to REDCap portal
Importance: High

Hi Ashley,

Mariam is working on updating the intro language to the ACTIV Compound Portal (<https://redcap.ncats.nih.gov/redcap/surveys/index.php?s-DAE87WPTE7>) and will have it done today. Does that align with you all?

Best,
Christine

Christine Cutillo, MMCI
Data Science Lead
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health

[b6]

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, October 6, 2020 10:15 AM

APAR0000021729

To: Adam, Stacey (FNIH) [T] [b6]; Cutillo, Christine (NIH/NCATS) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]
Subject: RE: for your consideration: suggested edits to REDCap portal

Thanks, Stacey! Yes, Christine let's connect via email offline.

Thanks everyone!
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Tuesday, October 6, 2020 10:07 AM
To: Cutillo, Christine (NIH/NCATS) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]
Subject: RE: for your consideration: suggested edits to REDCap portal

Hi All,

I have not additional suggestions.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Cutillo, Christine (NIH/NCATS) [E] [b6]
Sent: Tuesday, October 6, 2020 9:40 AM
To: Menetski, Joseph (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]
Subject: RE: for your consideration: suggested edits to REDCap portal

Thanks, Joe. Do we need to wait for Stacey to weigh in too?

I spoke with Mariam and as soon as we have the finalized version of the text, it will be fairly streamlined – i.e., a few hours. I've attached the clean version here.

Ashley – once we hear from Stacey, let's touch base to plan/coordinate? Today or tomorrow sounds feasible.

Best,
Christine

Christine Cutillo, MMCI
Data Science Lead
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health

b6

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Menetski, Joseph (FNIH) [T] b6
Sent: Monday, October 5, 2020 8:57 PM
To: Parker, Ashley (NIH/OD) [E] b6; Cutillo, Christine (NIH/NCATS) [E] b6
Gadbois, Ellen (NIH/OD) [E] b6; Adam, Stacey (FNIH) [T] b6
Cc: Brodd, Lauren (NIH/OD) [E] b6; Colvis, Christine (NIH/NCATS) [E] b6;
Jonson, Samantha (NIH/NCATS) [E] b6
Subject: RE: for your consideration: suggested edits to REDCap portal

I like the new language, very clear. I am fine with substituting this whenever it is possible.

Thank you all for working thought this.

Joe

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Monday, October 5, 2020 3:41 PM
To: Cutillo, Christine (NIH/NCATS) [E] b6; Gadbois, Ellen (NIH/OD) [E] b6;
Menetski, Joseph (FNIH) [T] b6; Adam, Stacey (FNIH) [T] b6
Cc: Brodd, Lauren (NIH/OD) [E] b6; Colvis, Christine (NIH/NCATS) [E] b6;
Jonson, Samantha (NIH/NCATS) [E] b6
Subject: RE: for your consideration: suggested edits to REDCap portal

Hi All,

Jumping in here for a moment. Thanks, Christine! The changes to the NIH OD portal are also cleared and we planned to make those changes live once the ACTIV/RedCap edits were cleared by OGC. Many thanks to Ellen and everyone on the thread for moving this forward!

The links (now two separate buttons) on the [ACTIV website](#) and [NIH COVID page](#) are already updated to take submitters to the appropriate portal. It would be great if we could coordinate the updates to both portals on the same day – Christine please let us know if its feasible to make the revisions live by tomorrow or Wednesday? I'll work with the NIH OD team to ensure the updates happen close together if not the same day.

Again, thanks to everyone for moving this forward!

Thanks,
Ashley

From: Cutillo, Christine (NIH/NCATS) [E] b6
Sent: Monday, October 5, 2020 3:03 PM
To: Gadbois, Ellen (NIH/OD) [E] b6; Menetski, Joseph (FNIH) [T] b6
Cc: Brodd, Lauren (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6; Colvis, Christine (NIH/NCATS) [E] b6; Adam, Stacey (FNIH) [T] b6; Jonson, Samantha

(NIH/NCATS) [E] [b6]

Subject: RE: for your consideration: suggested edits to REDCap portal

Dear Joe & Stacey,

Let us know when this has been finalized and we can work with Mariam to update the RedCap intro page.

Best,
Christine

Christine Cutillo, MMCi
Data Science Lead
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health

[b6]

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Gadbois, Ellen (NIH/OD) [E] [b6]

Sent: Monday, October 5, 2020 1:40 PM

To: Menetski, Joseph (FNIH) [T] [b6]

Cc: Brodd, Lauren (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Cutillo, Christine (NIH/NCATS) [E] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]

Subject: RE: for your consideration: suggested edits to REDCap portal

Oops use this. There was a typo. Thanks

From: Gadbois, Ellen (NIH/OD) [E]

Sent: Monday, October 5, 2020 12:35 PM

To: Menetski, Joseph (FNIH) [T] [b6]

Cc: Brodd, Lauren (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Cutillo, Christine (NIH/NCATS) [E] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]

Subject: RE: for your consideration: suggested edits to REDCap portal

Dear Joe,

I have what I think is clearer language from OGC to describe the potential for public disclosure. So attached is a draft similar to what I sent you before--it has all of the edits that I proposed earlier, plus revised language on possible disclosure. I also propose a few more minor edits for clarity.

If this looks OK with you, NCATS can go ahead and make the changes on the webpage. FYI Ashley and I spoke about whether there should be additional text added to address the NIH IRP's concerns about losing control of their product development and/or IP, but we think that's probably best handled where it comes up rather than being on this webpage.

Thanks very much,
Ellen

From: Menetski, Joseph (FNIH) [T] [b6]

Sent: Friday, September 25, 2020 9:50 AM

To: Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]

Cc: Colvis, Christine (NIH/NCATS) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]

Subject: RE: for your consideration: suggested edits to REDCap portal

Happy to jump on a call to discuss, if that would help. Maybe before your discussion with OGC.

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Friday, September 25, 2020 9:41 AM

To: Menetski, Joseph (FNIH) [T] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]

Cc: Colvis, Christine (NIH/NCATS) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]

Subject: RE: for your consideration: suggested edits to REDCap portal

Thanks, Joe for the quick review! Ellen and others will know how FOIA may or may not apply here and if it's possible for someone to request full information about a particular submission. It may be best to have this section cleared by OGC before making public.

Thanks again,
Ashley

From: Menetski, Joseph (FNIH) [T] [b6]

Sent: Friday, September 25, 2020 9:30 AM

To: Gadbois, Ellen (NIH/OD) [E] [b6]

Cc: Parker, Ashley (NIH/OD) [E] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]

Subject: RE: for your consideration: suggested edits to REDCap portal

Hi Ellen,

We only have one comment (from me) about the intent to make the submission public. We do not expect to do this, and I think we made that statement in the original language. I think we need to make the statement highlighted reflect that expectation.

I would be happy to discuss this further.

Joe

From: Gadbois, Ellen (NIH/OD) [E] [b6]

Sent: Wednesday, September 23, 2020 4:13 PM

To: Menetski, Joseph (FNIH) [T] [b6]; Cutillo, Christine (NIH/NCATS) [E] [b6]; Adam,

Stacey (FNIH) [T] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Wholley, David (FNIH)

[T] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]

Cc: Culp, Michelle (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,

Lauren (NIH/OD) [E] [b6]

Subject: for your consideration: suggested edits to REDCap portal

Hi folks,

I am picking up on this old email thread and adding one twist. Ashley Parker, Lauren Brood, Renate Myles, and I are in the process of getting some updates made to the [NIH OD COVID portal](#) in part to clarify which portal people should use for what purposes. As part of that work, we also looked at the [REDCap portal](#) webpage and have some proposed edits for consistency, as well as adding a blurb about the confidentiality arrangement discussed below. Can you see if these attached proposed edits are accurate and consider whether they are useful? Of particular note, it removes references to submitting vaccine info to the REDCap portal and focuses on therapeutics. And based on the conversation below between Christine Cutillo and Joe, maybe there are other instructions you want to add or link to the portal.

Happy to chat about this.

Best,
Ellen

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Thursday, August 20, 2020 4:37 PM
To: Cutillo, Christine (NIH/NCATS) [E] [b6]
Cc: Colvis, Christine (NIH/NCATS) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6];
Culp, Michelle (NIH/OD) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6];
Alvarez, Rosa Maria <rosalvarez@deloitte.com>
Subject: RE: REDCap confidentiality--clarifying...

Hi Christine,

Got it. Actually I thought the attached document had been finalized, but I cannot find a file in my possession labeled final. So, lets call this finalized now.

Also, yes, please feel free to add the lines below to any correspondence to increase clarity.

Just one more thing, we ask the submitters to only provide info that doesn't require a CDA. We provide an box to check if they have data but will only share under CDA. We do not have CDAs with the reviewers for the initial review. If a compound is interesting to the team, and has indicated that there is data, but requires a CDA, then we get CDAs signed by all parties.

So there is a CDA with the submitter and the FNIH, and a CDA from the FNIH with the reviewers (individual or institution). However, those are only executed if there is sufficient interest from the ACTIV review team to do so. So Ellen's comments below would need to be modified based on the current practice.

Best,

Joe

From: Cutillo, Christine (NIH/NCATS) [E] [b6]
Sent: Thursday, August 20, 2020 12:48 PM
To: Menetski, Joseph (FNIH) [T] [b6]
Cc: Colvis, Christine (NIH/NCATS) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6];
Culp, Michelle (NIH/OD) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6];
Alvarez, Rosa Maria <rosalvarez@deloitte.com>
Subject: RE: REDCap confidentiality--clarifying...

Dear Joe,

No that's not what I'm getting at; for further clarification/background:

As you recall from our prior discussions, the TransNIH Preclin WG is prioritizing projects within the IRP submitted to the COVID IRP dashboard. During our first wave of prioritization, we sent the ACTIV Compound Survey to about 25 PIs whose projects rose to the top as being potentially relevant and shovel ready. When we sent them the ACTIV Compound Survey, there was a lot of reticence re: how their information/data submitted to the Compound Survey would be used. We had previously asked you for language that outlines the use of the data, but you didn't have anything finalized at the time (end of June) and the below email chain was started by Ellen back at the end of July. We have finished our second wave of prioritization and will be sending out a similar email to IRP PIs, who have risen to the top of being able to move into the clinic ASAP, with a link to the ACTIV Compound Survey. This time around, we would like to provide IRP PIs additional information/assurances as we received many questions about this last time, so we'd like to heed them off for this round, if possible.

Has the attached been finalized and/or can we use the wording below (pulled from the attached) in the next email that goes out to IRP PIs (that rose to the top of the TransNIH Preclin WG prioritization based on ACTIV criteria) to provide them additional information/assurances?

Best,
Christine

ACTIV responsibilities to the submitter of the survey request:

ACTIV is a public-private partnership to develop therapies to end the pandemic. ACTIV is not a program to provide funding to individuals and organizations wishing to develop a therapy on their own. All therapy development within the ACTIV program will be done as a collaboration between government, academic and industry partners with decision making authority shared between the members of the partnership.

ACTIV does not expect to take possession of any therapeutic that has been suggested. The work to develop the therapy will be done in collaboration with the sponsor. ACTIV will work with the current owner of the therapy as would be needed to allow the therapy to be rapidly developed and distributed to patients in need of therapies. If a sponsor does not own the IP to the therapy, ACTIV will not be responsible for securing the appropriate contractual obligations to allow the sponsor to use the owner's IP.

Christine Cutillo, MMCI
Data Science Lead
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health
Phone [REDACTED] b6
[REDACTED] b6

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Menetski, Joseph (FNIH) [T] [REDACTED] b6

Sent: Thursday, August 20, 2020 12:35 PM

To: Cutillo, Christine (NIH/NCATS) [E] [REDACTED] b6

Cc: Colvis, Christine (NIH/NCATS) [E] [REDACTED] b6; Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6

Culp, Michelle (NIH/OD) [E] [REDACTED] b6; Jonson, Samantha (NIH/NCATS) [E] [REDACTED] b6

Alvarez, Rosa Maria <rosalvarez@deloitte.com>

Subject: RE: REDCap confidentiality--clarifying...

Christine,

We added these lines to the subsequent surveys (BSL3 survey). I think this can be added to the therapeutics survey too, is that what you are asking? We just need to ask Mariam to add them, I think, if we haven't don't it already.

What every we can do to make this clear is good.

Best,
Joe

From: Cutillo, Christine (NIH/NCATS) [E] [b6]
Sent: Thursday, August 20, 2020 12:27 PM
To: Menetski, Joseph (FNIH) [T] [b6]
Cc: Colvis, Christine (NIH/NCATS) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]
Culp, Michelle (NIH/OD) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]
Subject: RE: REDCap confidentiality--clarifying...

Dear Joe,

A reminder about this question.

Thanks in advance,
Christine

Christine Cutillo, MMCI
Data Science Lead
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health
Phone: [b6]
[b6]

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Cutillo, Christine (NIH/NCATS) [E]
Sent: Friday, August 14, 2020 2:39 PM
To: Menetski, Joseph (FNIH) [T] [b6]
Cc: Colvis, Christine (NIH/NCATS) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]
Culp, Michelle (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: REDCap confidentiality--clarifying...

Dear Joe,

Has the attached been finalized and/or can we use the wording below (pulled from the attached) in the next email that goes out to IRP PIs (that rose to the top of the TransNIH Preclin WG prioritization based on ACTIV criteria) to provide them additional information/assurances? We did receive questions about this last time, so we'd like to heed them off for this round, if possible.

Best,
Christine

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ACTIV does not expect to take possession of any therapeutic that has been suggested. The work to develop the therapy will be done in collaboration with the sponsor. ACTIV will work with the current owner of the therapy as would be needed to allow the therapy to be rapidly developed and distributed to patients in need of therapies. If a sponsor does not own the IP to the therapy, ACTIV will not be responsible for securing the appropriate contractual obligations to allow the sponsor to use the owner's IP.

Christine Cutillo, MMCI
Data Science Lead
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health
Phone [REDACTED] b6
[REDACTED] b6

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Menetski, Joseph (FNIH) [T] [REDACTED] b6
Sent: Friday, July 24, 2020 11:45 AM
To: Colvis, Christine (NIH/NCATS) [E] [REDACTED] b6; Cutillo, Christine (NIH/NCATS) [E]
[REDACTED] b6; Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6; Culp, Michelle (NIH/OD) [E]
[REDACTED] b6; Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Cc: Menetski, Joseph (FNIH) [T] [REDACTED] b6
Subject: FW: REDCap confidentiality--clarifying...

Dear Christine Colvis,

If you are good with the changes in this document, I am fine with it. Can we add this to the current Redcap survey? I remember having this as optional text to read, if someone wanted to (follow the link)? I guess this got stalled and we need to decide how to distribute, as Ellen suggests.

Do you want to get this group together to discuss?

I can get a copy of the CDA template, I just need to get it.

Best,
Joe

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Sent: Friday, July 24, 2020 10:43 AM
To: Menetski, Joseph (FNIH) [T] [REDACTED] b6
Cc: Cutillo, Christine (NIH/NCATS) [E] [REDACTED] b6; Culp, Michelle (NIH/OD) [E] [REDACTED] b6
Parker, Ashley (NIH/OD) [E] [REDACTED] b6; Colvis, Christine (NIH/NCATS) [E] [REDACTED] b6
Subject: RE: REDCap confidentiality--clarifying...

Thanks very much, Joe. A few more questions (always easier to ask questions than to do the real work...):

- 1) The attached Expectations document has redline in it—is someone going to put it in final soon? I think it would be good for Christine Cutillo to send it on to the intramural folks once it is finalized, along with my Joe-approved blurb below.
- 2) Will the Expectations document go up on the REDCap compound survey webpage somewhere, or will you just send it out if people ask?
- 3) Can you also send me the template CDA that reviewers sign?

Best,
Ellen

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Thursday, July 23, 2020 5:27 PM
To: Gadbois, Ellen (NIH/OD) [E] [b6]
Cc: Cutillo, Christine (NIH/NCATS) [E] [b6]; Culp, Michelle (NIH/OD) [b6]
Parker, Ashley (NIH/OD) [E] [b6]; Colvis, Christine (NIH/NCATS) [E]
Subject: RE: REDCap confidentiality--clarifying...

Dear Ellen,

I think your statement below is good.

I shared something with Christine Colvis a bit ago (time no longer seems to register). I have attached the email to this. Perhaps this might help?

Joe

From: Gadbois, Ellen (NIH/OD) [E] [b6]
Sent: Thursday, July 23, 2020 5:05 PM
To: Menetski, Joseph (FNIH) [T] [b6]
Cc: Cutillo, Christine (NIH/NCATS) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Subject: REDCap confidentiality--clarifying...

Hi Joe,

I hope you're having a manageable week. I'm writing to follow up on our prior discussion about confidentiality of data submitted through the REDCap compound survey. Christine Cutillo (cc'd) reports that there are intramural investigators who are still worried about what could happen with information they might provide to ACTIV via the portal. I thought it would help to give them a description blessed by FNIH. Here's what I wrote up about our earlier conversation:

"Those who decide to fill out the REDCap survey are given the opportunity to provide the data for review under a confidentiality disclosure agreement, which is signed by those on the ACTIV agenda selection/prioritization group reviewing that information. FNIH asks the ACTIV reviewers to recuse themselves if they have additional knowledge about the compound, or feel too close to it."

Is that correct, and is there any other details you could add to it? Also, could you provide a copy of the CDA that reviewers sign?

Thanks,
Ellen

Ellen L. Gadbois, Ph.D.

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National Institutes of Health
Turning Discovery Into Health

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 11/11/2020 1:58:24 PM
To: Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeling]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholley]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6] Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; neato001@umn.edu; [b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6] Lisbeth Jørgensen [b6] Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6] Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]
Subject: Canceled: ACTIV-2/-3 Trial Oversight Committee Meeting
Location: https://fnih.zoom.us/[b6]

Start: 11/11/2020 8:00:00 PM
End: 11/11/2020 9:00:00 PM
Show Time As: Free

Recurrence: Weekly

every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Stein, Peter (FDA/CDER); Erbeling, Emily (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Enca Ollmann Saphire; Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; [b6] Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS)

Dear ACTIV-2/-3 TOC Members,

After speaking with the co-chairs, since we have an ad hoc meeting earlier in the day for ACTIV-2 with Lilly and Cliff let me know there are no pressing issues for ACTIV-3, we have decided to cancel this meeting for today to allow many of you a bit more of your holiday back.

Thank you to all our Veterans! And thank you to all of you for all your hard work!

Thanks,
Stacey

Join Zoom Meeting
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 11/4/2020 7:41:33 PM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6]; [b6]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Bethany Stokes [b6]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]
Subject: ACTIV-2/-3 Trial Oversight Committee Meeting

Attachments. ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201104.pdf; SOP for Communications about Significant Updates from ACTIV 11042020v3.docx

Location: <https://fnih.zoom.us/j/91811111111> **b6**

Start: 11/4/2020 8:00:00 PM

End: 11/4/2020 9:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Higgs, Elizabeth (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; **b6** Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Bethany Stokes; Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS)

Dear ACTIV-2/-3 TOC Members,

Please find the materials for the for today's meeting.

Thanks,
Stacey

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Meeting ID: **b6**
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Sent: 10/6/2020 4:09:15 PM
To: Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2fbf13-walsher]
CC: Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal
Attachments: Proposed revised language for ACTIV portal 5 Oct 2020.2-clean.docx

Hi Beth,

NCATS is updating the ACTIV portal and this will be finalized today. Thanks so much for updating the NIH portal

From: Walsh, Elizabeth (NIH/OD) [E] [b6]
Sent: Monday, October 5, 2020 3:56 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Schwetz, Tara (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Thanks for letting us know.

Best,
Beth

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Monday, October 5, 2020 at 3:52 PM
To: "Walsh, Elizabeth (NIH/OD) [E]" [b6]
Cc: "Schwetz, Tara (NIH/OD) [E]" [b6]; "Brodd, Lauren (NIH/OD) [E]" [b6]; "Myles, Renate (NIH/OD) [E]" [b6]; "Gadbois, Ellen (NIH/OD) [E]" [b6]
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Beth,

Attached are the revisions cleared by OGC for the ACTIV portal and I provided the contact email for technical issues below. I'm waiting to hear back if the updates will happen tomorrow or Wednesday.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, September 29, 2020 7:04 PM
To: Walsh, Elizabeth (NIH/OD) [E] [b6]
Cc: Schwetz, Tara (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Myles,

Renate (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]

Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Beth,

If companies have technical issues with the ACTIV portal they can email activ_submission@fnih.org.

As you know, Ellen is working with OGC to confirm/clear additional language on the ACTIV portal and OGC indicated they will review tomorrow. We will keep you updated on this clearance to ensure the live updates to both portals can be done on the same day – hopefully this can happen within the next day couple of days.

Thanks again,
Ashley

From: Parker, Ashley (NIH/OD) [E]

Sent: Tuesday, September 29, 2020 8:14 AM

To: Walsh, Elizabeth (NIH/OD) [E] [b6]

Cc: Schwetz, Tara (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]

Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Beth,

Thanks so much for the update. Ellen is working closely with the ACTIV group on finalizing the ACTIV portal language. We are checking on the response to your question below regarding a contact email for technical issues — to my understanding FNih does not have the bandwidth or staff to manage an inbox for the ACTIV portal but we are cross checking with their team.

We've received minor edits to the ACTIV portal and we are asking NCATS how soon the changes can go live. I think it would be good to have both portal updates go live on the same day.

I will circle back on both responses today.

Thanks,
Ashley

On Sep 29, 2020, at 6:26 AM, Walsh, Elizabeth (NIH/OD) [E] [b6] wrote:

Hi Ashley,

We've made edits to the document and it's ready to post. I just need to know what email address you would like to list on the portal page for people who have issues with the Redcap survey. Will it be foundation@fnih.org? The final language is attached, and I can send it on to Michael for posting once I have the email. When will the new language for the Redcap survey be online?

Best,
Beth

From: "Parker, Ashley (NIH/OD) [E]" [b6]

Date: Monday, September 28, 2020 at 7:49 AM

To: "Walsh, Elizabeth (NIH/OD) [E]" [b6], "Schwetz, Tara (NIH/OD) [E]"

[b6]

Cc: "Brodd, Lauren (NIH/OD) [E]" [b6], "Myles, Renate (NIH/OD) [E]"

[b6]

Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Good morning,

I'm following up on the note below — are there any concerns with moving forward with changes to the NIH portal?

Thanks,
Ashley

On Sep 22, 2020, at 3:11 PM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

Hi Beth and Tara,

Apologies for the delay. To provide a quick update to option 2, with many thanks to Renate, OCPL is in the process of adding two buttons on the ACTIV webpage, one for therapeutics that links to the ACTIV portal and a second for vaccines and other candidates that will link to the NIH portal. A similar change will be made on the NIH COVID page to ensure the public clearly knows where to click for therapeutics vs. other submissions.

We took the first stab at providing recommended changes to the current NIH portal language attached and we are simultaneously vetting changes to the ACTIV portal to ensure there's no confusion about what compounds should be submitted to each portal. I will share the revised ACTIV portal language once this is cleared by ACTIV and NCATS.

Please let me know if you have any questions.

Thanks,
Ashley

From: Walsh, Elizabeth (NIH/OD) [E] [b6]

Sent: Friday, September 18, 2020 11:13 AM

To: Parker, Ashley (NIH/OD) [E] [b6]

Cc: Brodd, Lauren (NIH/OD) [E]

Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Sounds good. Happy Friday!

From: "Parker, Ashley (NIH/OD) [E]" [b6]

Date: Friday, September 18, 2020 at 11:11 AM

To: "Walsh, Elizabeth (NIH/OD) [E]" [b6]

Cc: "Brodd, Lauren (NIH/OD) [E]" [b6]

Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Got it – we will work with OCPL on this and circle back with you and Tara. I think we can continue to made progress via email – thanks!

Ashley

From: Walsh, Elizabeth (NIH/OD) [E] [b6]
Sent: Friday, September 18, 2020 9:59 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Ashley,

There isn't an OD COVID-19 Portal page. The portal can only be accessed by clicking on a link such as is on the ACTIV or RADx pages. I think the only other place it is listed in a general way is on the main COVID-19 page, but you'd have to check with OCPL on that. Once the language for the links has been established, you can ask them to update any other pages where the portal link appears. I'm free on Monday between 11:30 and 1:30 if there's a time in there that works for you to meet, if needed.

Beth

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Friday, September 18, 2020 at 9:26 AM
To: "Walsh, Elizabeth (NIH/OD) [E]" [b6]
Cc: "Brodd, Lauren (NIH/OD) [E]" [b6]
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Beth,

If Monday is better for you we can schedule a time to discuss then or we can continue to handle over email.

We will make the changes on our end for the ACTIV website to ensure we implement two buttons, one for preclinical and clinical therapeutics (linking to the ACTIV portal) and a separate button for vaccines and others (linking to the NIH portal) however it's important to ensure similar changes are made on the NIH portal page hence my note to you and Tara for option 2.

Lauren and I are working on editing language for the ACTIV section of the NIH page and we will send those recommendations today. Given these changes with two links there should be no need for ACTIV submissions to come through the NIH portal but now go directly to ACTIV. I am happy to raise to the ACTIV WG leads to add a contact email to the ACTIV/RedCap link. Currently, companies contact FNIH directly if they have questions.

Thanks,
Ashley

From: Walsh, Elizabeth (NIH/OD) [E] [b6]
Sent: Friday, September 18, 2020 9:02 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E]

b6

Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Ashley,

I'll have to play it by ear today as I have some larger items that are due today that still need work. Happy to have a call on Monday if needed. My suggestion would be to have one button that says "Submit Your Therapeutic Candidates Here" and one button that says "Submit Your Vaccine Candidate or Other Ideas Here" on the ACTIV homepage as well as anywhere else there is a Redcap survey link. For stuff relevant to ACTIV that still comes in through the OD portal, I can continue to shunt that through the already established channel.

I think it would also be prudent to put a contact email address on the Redcap survey, since a human won't be sending out the link any longer. If people have questions or issues, right now there's nowhere for them to go.

Best,
Beth

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Friday, September 18, 2020 at 8:03 AM
To: "Walsh, Elizabeth (NIH/OD) [E]" [b6] "Brodd, Lauren (NIH/OD) [E]" [b6]
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Looping in Lauren in case she has time to join us? Lauren is helping us manage updates to the ACTIV website.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, September 18, 2020 7:57 AM
To: Walsh, Elizabeth (NIH/OD) [E] [b6]
Subject: re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Beth,

Please let me know if you have time today for a call. I'm available between 11-1pm or after 2:30pm.

Thanks,
Ashley

Begin forwarded message:

From: "Schwetz, Tara (NIH/OD) [E]" [b6]
Date: September 18, 2020 at 12:21:33 AM EDT
To: "Parker, Ashley (NIH/OD) [E]" [b6], "Walsh, Elizabeth (NIH/OD) [E]" [b6]

APAR0000021736

Cc: "Brodd, Lauren (NIH/OD) [E]" [b6]
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Ashley,

Apologies for the delayed response – this email must have gotten shunted to my draft folder during one of my (regular) Outlook crashes because I just found it there!

This is really unfortunate to hear, as I think there could/should have been better coordination and communication on this (especially since you weren't even aware it was live!). That said, since it's already live, I suppose the best option is option 2. Regardless, there will still be confusion about what to submit where and you all will still get items that you would automatically rule out and/or that will be irrelevant.

Regarding ExecSec, the process is that they refer people to the portal (recall that it's a way to ease email traffic as well), so it seems a bit circular to refer people to ExecSec, who would in turn refer them to the portal. Obviously, we can change the process; however, I'm not sure ExecSec has the capacity or knowledge to make these determinations. Plus, we have the infrastructure of the review group.

Would you please work with Beth to determine how best to structure this and what terminology/language to use to do so? Thanks for keeping us in the loop.

Best,

Tara A. Schwetz, PhD

Associate Deputy Director, NIH

A: Building 1, Room 138

P: [b6] | M: [b6]

<image003.png>

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Tuesday, September 15, 2020 at 4:28 PM
To: "Walsh, Elizabeth (NIH/OD) [E]" [b6]
Tara Schwetz [b6]
Cc: "Brodd, Lauren (NIH/OD) [E]" [b6]
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Tara and Beth,

I have new news. Lauren Brodd and I are working closely with OCPL to review and provide updates to the ACTIV website and we noticed the link to the ACTIV portal is publicly available as of 9/10. The ACTIV working group pages were posted at the end of last week and this update included the link to the ACTIV clinical and preclinical portal/RedCap survey approved by FNIH. The ACTIV portal currently lives on the [Preclinical WG page](#) and [Clinical Tx WG page](#).

Apologies for not noticing this sooner! (hence my original question to the war room) – this question was in the draft but was later approved and found today during our weekly review.

Tara – if you agree, I will follow up with the war room tomorrow morning to let them know the ACTIV portal is live and we are working with your team to ensure the submission processes are clearly defined and synched?

Below are a few options for consideration knowing we would need to consult OCPL for any changes to the ACTIV website once we have a clear path forward. These are only ideas but defer to your team if there are other recommendations.

- **Option 1: Do nothing and continue the triage process for ACTIV via OD and then send to FNIH to send the ACTIV/RedCap survey**
 - **Pros:**
 - Current process in place for companies interested in submitting compounds to ACTIV without completing the longer ACTIV/RedCap survey.
 - **Cons:**
 - Now two portals for preclinical and clinical therapeutic submissions which could be confusing to users
 - Selected companies routed to ACTIV currently submit information twice (NIH portal and ACTIV/RedCap) although the ACTIV/RedCap survey takes longer.
 - Interested companies go through several channels before receiving email with ACTIV/RedCap link that is now available on the ACTIV website.
- **Option 2: Ask OCPL to add the ACTIV/RedCap link to the main ACTIV webpage “submit your ideas” (for companies who want to submit preclinical or clinical therapeutic compounds) and keep the existing link to NIH portal (for companies who want to submit vaccines, other). Make any necessary edits to the current ACTIV language provided on the NIH portal.**
 - **Pros:**
 - Interested companies can submit preclinical and clinical therapeutics directly to ACTIV without going through the NIH portal and triage process to receive the link,
 - Any submissions to the NIH portal that should go to ACTIV can be directed to complete the ACTIV/RedCap link on the website.

- Should limit the number of therapeutic submissions to the NIH portal – limit the number for review and triage.
- Any follow up questions regarding submissions to ACTIV/RedCap can be directed to FNIH agent prioritization leads for response.
- **Cons:**
 - Links to 2 different portals could be confusing to users if not clearly defined.
 - Providing link to NIH portal (diagnostics, technologies, vaccines, others) on the ACTIV webpage could be confusing given there is no agent prioritization role for ACTIV beyond therapeutics.
- **Option 3: Ask OCPL to remove the existing NIH portal link from the ACTIV website and replace with ACTIV/RedCap link. Make any necessary edits to the current ACTIV language provided on the NIH portal.**
 - **Pros:**
 - One link available for ACTIV submissions may avoid confusion.
 - Interested companies can submit preclinical and clinical therapeutics directly to ACTIV agent information without going through the NIH portal and triage process to receive the link.
 - Any submissions to the NIH portal that should go to ACTIV can be directed to complete the ACTIV/RedCap link on the website.
 - Should limit the number of therapeutic submissions to the NIH portal – limit the number for review and triage.
 - Vaccines, diagnostics, others continue to come to the NIH portal via one location NIH COVID page.
 - **Cons:**
 - ACTIV/RedCap may potentially receive compounds beyond therapeutics (vaccines, diagnostics, others) not relevant for ACTIV

Beth – for the irrelevant content coming through the NIH portal, would it be useful to have all general submissions routed directly to ES and only have the serious inquiries for diagnostics, vaccines, technologies reviewed by the cross-NIH team? It may require having a click system for general inquiries, vaccines, diagnostics that leads to a series of targeted questions to weed out the irrelevant submissions although I understand this creates more work! Sighs! 😊 The current platform could be too easy and potentially invites those types of general

submissions which is fine but seems more appropriate for ES to sort – just a thought.

Thanks,
Ashley

From: Walsh, Elizabeth (NIH/OD) [E] [b6]
Sent: Tuesday, September 15, 2020 6:23 AM
To: Schwetz, Tara (NIH/OD) [E] [b6] >; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Tara and Ashley,

For context, 593 of 724 submissions to date have been labeled as preclinical, therapeutic, or "other". I've passed submissions from each of these categories on to ACTIV in the past. Of the 593 submissions, about 20% were approved for dissemination by the review group, and still fewer were appropriate for ACTIV, somewhere between 10% and 15%.

Once the portal was public for a few weeks, we started to receive and have continued to receive a lot of irrelevant content (e.g., anecdotal stories, Fauci/Collins fan mail, and questions that need to be redirected to other channels). These types of responses are the bulk of what is received through the portal now, and it can take a significant amount of time for someone to go through them.

Best,
Beth

From: "Schwetz, Tara (NIH/OD) [E]" [b6]
Date: Monday, September 14, 2020 at 11:31 PM
To: "Parker, Ashley (NIH/OD) [E]" [b6]
Cc: "Walsh, Elizabeth (NIH/OD) [E]" [b6]
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

The clarity is definitely a big piece to consider. Additionally, we are still receiving quite a number of submissions that we would not have any interest in moving forward with (low quality/scientific rigor). What I don't know is how many of these are tx vs. vx, dx, or other. My guess is the tx submissions are a good chunk of these. Looping in Beth to confirm though.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: [b6] | M: [b6]

<image005.png>

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Monday, September 14, 2020 at 11:24 PM
To: Tara Schwetz [b6]
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

To my understanding, the goal for making the ACTIV portal/RedCap survey public is to allow companies direct access to submit detailed information about "therapeutic" compounds — this information is needed for the ACTIV prioritization process.

The ACTIV portal is specifically for preclinical and clinical therapeutics but nothing else. Vaccines, diagnostics, and other general submissions are not appropriate.

I agree — having two portals is already somewhat confusing and companies who are vetted through the NIH portal may feel confused after receiving a follow-up email to complete the ACTIV survey for a therapeutic compound they've already submitted. If ACTIV wants to move forward with making the link public maybe we'll need a "click here to submit a preclinical or clinical therapeutic agent to ACTIV/FNIH" with link to RedCap on the ACTIV website and NIH portal page but would need a "click here for vaccines, diagnostics, other technologies to link to the NIH portal and edit ACTIV language?" Renate will likely have better ideas!

I have no preference here but agree the process should be streamlined and easy for a submitter to understand. It's also tough to manage the changing landscape —ACTIV initially accepted vaccine candidates but now defer to NIAID now that the Vaccines WG ceased operations as of July 31st and currently meet on an ad hoc basis.

Please let me know if you need any additional info.

Thanks,
Ashley

On Sep 14, 2020, at 9:55 PM, Schwetz, Tara (NIH/OD) [E]

[b6]

wrote:

OK, thanks. What is the goal of making the ACTIV portal public? Are the WGs wanting to invite broad submission? We'll have to discuss how best to link and communicate this, as I do worry this could get confusing to people.

Best,

Tara A. Schwetz, PhD

Associate Deputy Director, NIH

A: Building 1, Room 138

P: [b6]

M: [b6]

<image001.png>

From: "Parker, Ashley (NIH/OD) [E]"

[b6]

Date: Monday, September 14, 2020 at 6:19 PM

To: Tara Schwetz [b6]

Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Tara,

For background, there have been discussions about whether or not the ACTIV portal developed by the ACTIV preclinical and clinical WGs and NCATS should be made public on the ACTIV website. This is independent of the NIH portal and submissions process although we can discuss options for streamlining if ACTIV decides to make it public.

I didn't think we needed to discuss any efforts to streamline/sync the efforts beyond the ongoing process before knowing if ACTIV would like to make this available or continue to send as "invite only." I planned to touch base with you and Beth after knowing what decision ACTIV decides to move forward with but please let me know if you have any questions.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]

Sent: Monday, September 14, 2020 12:37 PM

To: Tabak, Lawrence (NIH/OD) [E]

[b6]

Collins, Francis (NIH/OD)

[E] [b6]; Wholley, David (FNIH) [T]

b6; Freire, Maria (FNIH) [T]
Austin, Christopher (NIH/NCATS)
[E] **b6**
Cc: Gadbois, Ellen (NIH/OD) [E]
b6; Schwetz, Tara (NIH/OD) [E]
Subject: RE: ACTIV COVID-19 Clinical and Preclinical
Compound Portal

Also, the NIH portal (not specific to ACTIV but includes RADx, others) was put in place several months before the ACTIV portal was developed. They are only synched with the NIH portal submissions vetted for ACTIV receiving a link to complete the ACTIV survey.

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, September 14, 2020 12:33 PM
To: Tabak, Lawrence (NIH/OD) [E]
b6; Collins, Francis (NIH/OD)
[E] <**b6**>; Wholley, David (FNIH) [T]
b6; Freire, Maria (FNIH) [T]
Austin, Christopher (NIH/NCATS)
[E] **b6**
Cc: Gadbois, Ellen (NIH/OD) [E]
b6; Schwetz, Tara (NIH/OD) [E]
Subject: RE: ACTIV COVID-19 Clinical and Preclinical
Compound Portal

Not related. The information submitted to the ACTIV portal is used for the WGs to prioritize compounds and contains detailed information. The NIH portal has very limited information about the compounds, not sufficient for the agent prioritization process.

No issues with proprietary information as submitters must provide consent.

Hopefully this is helpful context.

Thanks,
Ashley

From: Tabak, Lawrence (NIH/OD) [E]
b6
Sent: Monday, September 14, 2020 12:28 PM
To: Parker, Ashley (NIH/OD) [E]
b6; Collins, Francis (NIH/OD) [E]
b6; Wholley, David (FNIH) [T]
Freire, Maria (FNIH) [T]
b6; Austin, Christopher (NIH/NCATS)
[E] **b6**
Cc: Gadbois, Ellen (NIH/OD) [E]

b6

; Schwetz, Tara (NIH/OD) [E]

Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

How does this relate to the NIH portal? I thought they were synched up. Are there still proprietary concerns? (cc'ing Tara who has dealt with that issue for NIH portal).

From: "Parker, Ashley (NIH/OD) [E]"

b6

Date: Monday, September 14, 2020 at 12:21 PM

To: Francis Collins [b6], "Tabak, Lawrence (NIH/OD) [E]"

b6

, "Wholley, David (FNIH)

[T]" [b6], "Freire, Maria (FNIH)

[T]" "Austin, Christopher

(NIH/NCATS) [E]" [b6]

Cc: "Gadbois, Ellen (NIH/OD) [E]"

b6

Subject: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi All,

If we have time on Wednesday, could we discuss if ACTIV would like to make the ACTIV COVID-19 Clinical and Preclinical Compound Portal also known as the RedCap survey public? The link to the ACTIV portal is currently shared via email to submitters who are vetted through the NIH COVID 19 Candidate and Technologies Portal and when companies send emails to Francis, Janet, FNIH, etc. to inquire about submitting their compound(s) for ACTIV.

This question was raised a while ago and was recently brought to my attention for follow-up.

Thanks,
Ashley

<Draft revised language for NIH COVID-19 portal 9-22-2020.docx>

<2020-09-29_Revised language for COVID-19 portal_final.docx>

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/19/2020 2:39:55 PM
To: Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6] [b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6] Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Kelly Beazley [b6]
Subject: ACTIV-2/-3 Trial Oversight Committee Meeting
Location: https://fnih.zoom.us/j/[b6]

Start: 10/23/2020 2:00:00 PM
End: 10/23/2020 3:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Woodcock, Janet (FDA/CDER); Wholley, David (FNIH) [T]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; [b6] Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Kelly Beazley

Dear ACTIV-2/-3 TOC Members,

Thank you to all who responded so quickly based on the current quorum. This seems to be the best time for the reschedule.
Friday - 10-11am ET

Thanks,
Stacey

Join Zoom Meeting

<https://fnih.zoom.us/> [b6]

Meeting ID: [b6]

Password: [b6]

One tap mobile

[b6] US (New York)
[b6] US (Germantown)

Dial by your location

b6

US (New York)
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US (Chicago)
US (Houston)
US (San Jose)
US (San Jose)
US (Tacoma)

Meeting ID: [b6]

Password: [b6]

Find your local number: <https://fnih.zoom.us/> [b6]

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/15/2020 11:49:07 AM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponeIm]
Subject: Re: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Thanks, Lauren!

Ashley

On May 15, 2020, at 7:28 AM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Sounds good. And just to clarify, the co-chairs are listed in the document, just not designated as co-chairs, in case that wasn't clear from my last email!

Thanks!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:45 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Lauren,

Thank you so much for the thorough review. I will check with FNIH tomorrow morning on the two names listed in the document but not in the spreadsheets for Tx clinical.

Strange that co-chairs are not listed – I will add them as well and agree having the list of names alphabetized will be best.

I will circle back with Renate cc'ing you once I hear back from FNIH.

Thanks again,
Ashley

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:30 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Sorry for the multiple emails! Just noticed that 'updated' was spelled wrong in the attached file name, so reattached with correct spelling!

From: Brodd, Lauren (NIH/OD) [E]
Sent: Thursday, May 14, 2020 10:27 PM

APAR0000013226

To: Parker, Ashley (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Ashley,

I compared the excel sheets with the draft word document, and everyone that is listed in your excel sheet is listed in the draft word document. A few comments that I added to the word draft, but please review and feel free to delete/ignore if not needed:

- When I was cross checking the lists, I sorted the excel sheets in alphabetical order, and in doing so I noticed a few names in the draft document are not listed alphabetically. I made notes of that in the attached.
- I happened to notice that for one person (John Mellors), the last line of his affiliation is listed as University of Pittsburg *Department* of Medicine. Based on all the other listings, I think it should either be School of Medicine, or the Department of Medicine should be on the previous line. I also noted this in attached.
- I noticed that to co-chairs are not listed for the working groups, and I thought I recalled that being brought up in the email chains so I put a comment as a reminder (but again feel free to delete/ignore).

So basically if none of those things need to be pointed out, then ignore the draft I'm attaching, and you can let Renate know that the names checked out.

Also, in your Clinical Therapeutics worksheet, these two people were not listed, but are in the word document. I'm guessing they should be there because they are showing as additions in track changes in the word document, but please verify before you reply:

- David C. Goff, M.D., Ph.D., Director, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, NIH
- Yves Rosenberg, M.D., MPH, Branch Chief, Atherothrombosis and Coronary Artery Disease Branch, National Heart, Lung, and Blood Institute, NIH

Let me know if you have any questions or need anything else.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 5:31 PM

To: Brodd, Lauren (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Great – thank you.

Ashley

From: Brodd, Lauren (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 5:29 PM

To: Parker, Ashley (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Thanks for sending- will work on this and let you know.

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 5:24 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Lauren,

I am attaching the rosters for each working group. Could you please assist with cross checking the names listed on the excel spreadsheet for each working group with those to be listed on draft web page (Word doc)?

We want to ensure we do not miss anyone. If you find any names that need to be added, can you please add them in tracked changes?

Thank you,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 4:49 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E]
[b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Ashley:

Abbey and Greta at FNIH have been reviewing the list and sending me updates, but I would be grateful for an extra pair of eyes. I've captured new adds or deletions in tracked changes based on what they've sent me in the attached.

We also need to cross check those who gave us approval to post their names, but I think I can get Emma to do that.

Thanks so much,
Renate

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 4:33 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E]
[b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Happy to help if needed!

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 4:11 PM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: FW: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Renate,

Do you need help going through the list of working group members and adding those to the draft webpage or do you have Abbey or someone else helping with this?

I wanted to give Lauren a head start if this is needed.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 2:43 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
[b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E]
[b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E]
[b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good afternoon:

In the interest of time, I wanted to share the attached two items for both NIH and FNIH leadership review. Attached are:

- 1) Draft web content for a proposed NIH ACTIV web page:
 - Currently, the content is based primarily on publicly available information (mostly pulled from the release).
 - The only new content is the listing of the Executive Committee and Working Group members.
 - Having an ACTIV webpage will provide interested stakeholders with a central resource for ACTIV information, including releases, scientific papers, blogs, etc.; will point people to the scientific portal for submitting assets; and would allow us to provide status updates, as appropriate and as desired, on ACTIV developments.
 - This page can be expanded when we are ready to make more information public.
- 2) Draft ACTIV Communication and Legislative Strategy:
 - The strategy includes proposed tactics that could be developed in the near term, as well as longer lead items that we can prepare for now as we consider appropriate timing.

If it's helpful, we'd be happy to participate in a call to talk through these recommendations with you. We look forward to your feedback.

Best,
Renate

Renate Myles, MBA

Deputy Director, Public Affairs,
Office of External Relations and Public Liaison
National Intelligence Council
at [REDACTED] b6

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 7:16:53 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: 2020-05-13_Executive_Committee_Meeting_Summary rev2

Title should be ACTIV Executive Committee Meeting vs. Leadership meeting.

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 2:30 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: 2020-05-13_Executive_Committee_Meeting_Summary rev2

FYI, just about ready to press send but thought I'd check to see if action items look right

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 6:06:29 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Cheryl,

I should have crossed checked the emails you added to the list. Can we please include these corrections for Drs. Weinmann and Mensah when you add these emails to the spreadsheet?

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 1:17 PM
To: Weinmann, Gail (NIH/NHLBI) [E] [b6] Mensah, George (NIH/NHLBI) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6] Melencio, Cheryl (FNIH) [T] [b6]
Subject: Time sensitive: Making your ACTIV Participation Public

Hi Gail and George

I got a bounce back because somehow your e-mail addresses weren't quite correct in the original list, so I'm sending you this again.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 2:45:07 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV Executive Committee Teleconference

Location: <https://fnih.zoom.us/j/9181212121> b6

Start: 5/20/2020 7:30:00 PM

End: 5/20/2020 9:00:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/10/2021 7:08:29 PM
To: Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: NIH COVID Therapeutics Connection

Will do—thanks.

Ashley

From: Read, Sarah (NIH/NIAID) [E] [b6]
Sent: Wednesday, February 10, 2021 2:05 PM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Beigel, John (NIH) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: Re: NIH COVID Therapeutics Connection

Agree.

Sarah

From: "Wholley, David (FNIH) [T]" [b6]
Date: Wednesday, February 10, 2021 at 1:02:20 PM
To: "Parker, Ashley (NIH/OD) [E]" [b6], "Beigel, John (NIH) [E]" [b6], "Read, Sarah (NIH/NIAID) [E]" [b6], "Adam, Stacey (FNIH) [T]" [b6]
Subject: RE: NIH COVID Therapeutics Connection

I think that would be a good idea. Don't know what others think.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, February 10, 2021 11:43 AM
To: Wholley, David (FNIH) [T] [b6]; Beigel, John (NIH) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: NIH COVID Therapeutics Connection

Should I set the record straight by confirming this is not true and point to the prioritization process outlined on the Tx clinical WG page? ☺

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, February 10, 2021 11:38 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Beigel, John (NIH) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: NIH COVID Therapeutics Connection

Sure. Don't like the comment about FC being "personally involved in choosing" the therapeutics. But you know that...

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Wednesday, February 10, 2021 11:36 AM

To: Beigel, John (NIH) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]

Cc: Wholley, David (FNIH) [T] [b6]

Subject: RE: NIH COVID Therapeutics Connection

Thanks, John – totally agree, the email was strange. I will relay the information provided below to OLPA to share with Laura Friedel. As Stacey suggested, this note could be in reference to issues with manufacturing, hence conversations with BARDA and OWS and not the trial itself.

In any case, I will provide a response and follow-up if anything else is needed.

Thanks everyone,

Ashley

From: Beigel, John (NIH) [E] [b6]

Sent: Wednesday, February 10, 2021 11:26 AM

To: Read, Sarah (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]

Cc: Wholley, David (FNIH) [T] [b6]

Subject: Re: NIH COVID Therapeutics Connection

I am confused by that email. The request for additional help in the email is one of the reasons we added their product (lenzilumab) to ACTIV-5, as it would help move their program. They are currently in ACTIV-5 and we are enrolling into the arm that has lenzilumab. We had a call with the Humanigen CEO and other leadership last week and the week before. They have finished their company sponsored study, and will have a read out in late March. When we talked they wanted to know how we could combine data sets with their trial to boost the data (hopefully) supporting a EUA and their planned licensure. Enrollment is not as fast as any of us would like – but that affects most of our trials. So from our perspective, besides enrollment, the collaboration seems to be going well.

My sense is the email trail may be lagging behind the actual developments. But if there are any concerns any of the involved groups can reach out to me.

--

John Beigel, M.D.

Associate Director for Clinical Research

Division of Microbiology and Infectious Diseases

National Institute of Allergy and Infectious Diseases (NIAID)

Phone: [b6]

email: [b6]

From: "Read, Sarah (NIH/NIAID) [E]" [b6]

Date: Wednesday, February 10, 2021 at 11:13 AM

To: "Parker, Ashley (NIH/OD) [E]" [b6]; "Adam, Stacey (FNIH) [T]" [b6]

Cc: "Wholley, David (FNIH) [T]" [b6]; John Beigel [b6]

Subject: RE: NIH COVID Therapeutics Connection

Hi Ashley, I'm not aware of what, if any, issues there are. I'm copying John Beigel who leads the ACTIV5 team to make him aware and weigh in.

Thanks,
Sarah

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, February 10, 2021 11:06 AM
To: Read, Sarah (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: NIH COVID Therapeutics Connection

Hi Sarah and Stacey,

We received the congressional inquiry below regarding Lenzilumab and the request for NIH assistance to get them moving again. This request seemed strange to me given the agent is currently being tested in ACTIV-5 and I would think they are already linked with the appropriate NIH contacts.

Do you have any insight on what the issues are and if anyone at NIAID is in contact with this company? Cc'ing David for awareness.

Thanks,
Ashley

From: Robinson, Michael (NIH/OD) [E] [b6]
Sent: Wednesday, February 10, 2021 9:07 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: NIH COVID Therapeutics Connection

Ashley – Laura Berkson recommended I reach out to you regarding the below inquiry I received from Laura Friedel. I would be interested in your thoughts regarding next steps, as I don't know who in NIH should meet with this company or if a meeting is even appropriate.

Thanks for your time and help,
Mike

From: "Friedel, Laura (Appropriations)" <Laura_Friedel@appro.senate.gov>
Date: Tuesday, February 9, 2021 at 5:31:56 PM
To: "Robinson, Michael (NIH/OD) [E]" [b6]
Subject: NIH COVID Therapeutics Connection

Hi,

I met with this company several months back. They talked to OWS and BARDA. However, are now stuck in the mud a little bit regarding a therapeutic they're developing for COVID (which is in a Phase III trial now). They seem to think that NIH might be able to help them get moving again and that Dr. Collins has been personally involved in choosing some of the OWS therapeutics (CAVEAT: I don't know if that is true).

Is there anyone at NIH they could speak to about this project? Thanks!

Laura Friedel
Clerk

Committee on Appropriations
Subcommittee on Labor, HHS, and Education
136 Dirksen Senate Office Building
Washington DC 20510
202-224-0314

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 4:51:40 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: RE: Trial status

Apologies, I am making my way through emails.

For the BARDA portal for submissions from companies – the platform contractor is Bionic-BCG.

<https://www.medicalcountermeasures.gov/Request-BARDA-TechWatch-Meeting/>

I think we agree this is different from what Peter is describing below. If BARDA is in the process of developing a platform to also track CT information – I am unaware of these developments but hope to learn more about this.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 12:33 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: RE: Trial status

OK, no worries. I will bring it up on the war room call today.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 12:26 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: RE: Trial status

Hi David,

Thank you for sharing the information. Unfortunately, I was not on the call with BARDA and I am only aware of the BARDA portal to receive inquiries from companies versus the dashboard you've described below.

Did Larry join this call? If so, I am happy to follow up with him if needed or this can be raised on our war room call this afternoon?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 11:04 AM
To: Parker, Ashley (NIH/OD) [E] [b6]

Cc: Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]

Subject: FW: Trial status

Hi Ashley

FYI. This below is a discussion about trial trackers or “dashboards” that show you what trials are being conducted and with what agents. There are a bunch out there, including BioCentury and Faster Cures/Milken etc but they all seem to be somewhat incomplete as to capturing the number of trials and lack some important information: for example what trials have actually been launched (as opposed to funded or announced; according to FDA many trials have not launched), what their timeline is, and what their accrual status is. FDA has hired McKinsey to do a dashboard, but BIO has meanwhile come out with something that looks even better—yet these seem lacking too. As discussed on last night’s call, it would be really useful for ACTIV to get access to the ASPR/BARDA dashboard (this is different than the BARDA submissions portal you worked on). As I recall, Bob Disbrow and Robert Johnson said there would be no problem sharing this, but do you recall the details or could you find out? (share with whom, how and when?) I did not want to bother Francis with this. Thanks, David

From: Stein, Peter [b6]

Sent: Thursday, May 14, 2020 7:18 AM

To: Adam, Stacey (FNIH) [T] [b6]

Cc: Wholley, David (FNIH) [T] [b6]

Subject: RE: Trial status

Thanks Stacey – Janet and I have been discussing this in the background – so I’m trying also to reflect her input. I think we’re aligned that if the monoclonal master protocol can be rapidly completed and implemented, that would be the optimal approach – but it can’t delay what could be done outside of ACTIV.

Re dashboards – I will need to know relatively quickly, as I did have McKinsey do some work assuming it might be used by ACTIV – but I will need to know if ACTIV would have other resources instead. I think I can arrange a demonstration of the dashboard quite soon if that would be useful.

Peter

From: Adam, Stacey (FNIH) [T] [b6]

Sent: Wednesday, May 13, 2020 9:29 PM

To: Stein, Peter [b6]

Cc: Wholley, David N (NIH) [b6]

Subject: RE: Trial status

Hi Peter,

As always good to receive your message, I appreciate you letting me know about the dashboard McKinsey is building for FDA. We do know that BCG has also built something for the ASPR/BARDA group. We are inquiring to see if we can get access to the ASPR dashboard. In addition, I know that my boss, David Wholley, has been meeting with Janet today to discuss not only her enthusiasm for the mAbs master protocol, but also about potential resources that she might be able to help us with.

As for the mAb protocol, the co-chairs and I have begun strategizing quick paths forward. We chat more about these in our Master Protocol Subgroup on Friday.

In addition to that discussion Friday, I am cc'ing David here, as I am sure he is in a much better position to discuss with you what he and Janet have been working on to assist the efforts of our WG.

Thank you again for your outreach,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Stein, Peter [b6]
Sent: Wednesday, May 13, 2020 7:11 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: Trial status

Stacey,

FDA is building (with McKinsey as consultants) a dashboard that pulls in a variety of sources of trial information for COVID (ct.gov, EU sources, etc.) – and is pretty versatile. I understand there are a number of different teams doing the same thing. Having a comprehensive dashboard of this sort is important. Let me know where this stands re ACTIV – we can have McKinsey provide this (we'd have to discuss funding) – if NIH doesn't already have this coming available. I think the more important component is finding sources for trial status. We have internal information, of course, on what INDs we've provided safe to proceed letters – but it's clear that despite giving the green light, as it were, many from weeks or longer before haven't started, and may not be starting. So – we need to have real-time access to trial status, recruitment and expected top line results.

I'd add that there seems to be a commitment I am hearing towards a master protocol for monoclonals – we need to have the design and implementation planning for that initiated as fast as we can – we should discuss how to get this done.

My Regards, peter

Peter P. Stein, MD
Director, Office of New Drugs, CDER/FDA
20903 New Hampshire Ave.
Silver Springs, MD 20993
[b6]

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 4:46:44 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Trial status

Yes, the BARDA portal platform contractor is Bionic – BCG.

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 11:20 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Trial status

More context: it is “the ASPR/BARDA dashboard that BCG did”

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 11:18 AM
To: Stein, Peter (FDA/CDER) [b6]
Cc: Wholley, David (FNIH) [T]
Subject: RE: Trial status

Hi Peter,

I know David has also already responded to you, but I didn’t want to think that I was ignoring your email.

As for the McKinsey dashboard, my apologies, I thought that was something you were doing for FDA that we could leverage. I would not necessarily engage them to do this for ACTIV until we understand whether or not we can get access to the dashboard from ASPR/BARDA that BCG has already done. I have seen a small snap shot of the data from that dashboard and I think it has what you would want. I don’t have the ability to share at this time, but we are working to see if we can get access. Mostly, I don’t want us recreating something if we don’t need to. Thank you however for looking in to helping the partnership. We truly value your contributions.

As for the monoclonals, we are going to discuss the path forward on those more on our Friday Master Protocol meeting. We have been working on a number of the questions Janet posed to us on the Executive Committee call already in the background.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Stein, Peter [b6]
Sent: Thursday, May 14, 2020 7:18 AM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: Trial status

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Peter

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 9:29 PM
To: Stein, Peter [b6]
Cc: Wholley, David N (NIH) [b6]
Subject: RE: Trial status

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Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Stein, Peter [b6]
Sent: Wednesday, May 13, 2020 7:11 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: Trial status

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trial information for COVID (ct.gov, EU sources, etc.) – and is pretty versatile. I understand there are a number of different teams doing the same thing. Having a comprehensive dashboard of this sort is important. Let me know where this stands re ACTIV – we can have McKinsey provide this (we'd have to discuss funding) – if NIH doesn't already have this coming available. I think the more important component is finding sources for trial status. We have internal information, of course, on what INDs we've provided safe to proceed letters – but it's clear that despite giving the green light, as it were, many from weeks or longer before haven't started, and may not be starting. So – we need to have real-time access to trial status, recruitment and expected top line results.

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My Regards, peter

Peter P. Stein, MD
Director, Office of New Drugs, CDER/FDA
20903 New Hampshire Ave.
Silver Springs, MD 20993

b6

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 4:41:15 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Information
Attachments: 20200508 BARDA Medical Countermeasures Response - Portfolio V2.pptx

Hi David,

The BARDA portal is public and can be found here
<https://www.medicalcountermeasures.gov/Request-BARDA-TechWatch-Meeting/>.

With regards to the slides Gary D. provided, these appear to be the list of awards BARDA has issued to companies which is also public. <https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx>

The information Peter provided seems to be different from the BARDA efforts, however as I mentioned I was not on the call with BARDA yesterday so there may be new developments that I am unaware of.

I hope this is useful.

Thanks,
Ashley



20200508 BARDA
Medical Counter...

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 11:08 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Information

How broadly can this be shared (the portal I assume is public, but the PP deck?) Can we assume Janet has seen it? And is the same as the ASPR/BARDA "tracker" or "dashboard" of clinical trials in progress we have been hearing about? Peter Stein has just been asking me about the latter.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 6:47 AM
To: Disbrow, Gary (OS/ASPR/BARDA) [b6]
Cc: Disbrow, Gary (OS/ASPR/BARDA) [b6]; Johnson, Robert (OS/ASPR/BARDA) [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E]

b6

Subject: RE: Information

Many thanks, Gary. The discussion was really helpful, and I appreciate this follow up.

Best, Francis

<< File: 20200508 BARDA Medical Countermeasures Response - Portfolio V2.pptx >>

From: Disbrow, Gary (OS/ASPR/BARDA)

b6

Sent: Thursday, May 14, 2020 4:10 AM

To: Collins, Francis (NIH/OD) [E]

b6

; Tabak, Lawrence (NIH/OD) [E]

b6

Cc: Disbrow, Gary (OS/ASPR/BARDA)

b6

bv>; Johnson, Robert (OS/ASPR/BARDA)

b6

Subject: Information

Francis and Larry,

Thank you for the discussion last night. We have a long standing, collaborative relationship with several institutes at NIH and look forward to the collaboration with the ACTIV Partnership.

The URL for our BARDA website is below. The page changes every several seconds and one has the icon to view the portfolio. The link to the portfolio page can also be found lower down on the page below the newsroom link.

<https://www.medicalcountermeasures.gov/>

Attached is a deck showing our investments across vaccines, therapeutics, diagnostics, rapidly deployable capabilities and non-clinical and other support. There will be one update today, we are supporting AZ for development of SARS-CoV-2 specific monoclonal antibodies.

<< File: 20200508 BARDA Medical Countermeasures Response - Portfolio V2.pptx >>

Regards,

Gary

Gary L. Disbrow Ph.D.

Deputy Assistant Secretary

Director, Medical Countermeasure Programs

Biomedical Advanced Research and Development Authority

BARDA

Assistant Secretary for Preparedness and Response ASPR

Department of Health and Human Services

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b6

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APAR0000013262

Note to contractors: nothing in this e-mail is intended to constitute contractual direction or to impact cost, price, or schedule contained in the contract. If the contractor believes there is an impact, the contractor must disregard that portion of the communication and contact the Contracting Officer for direction

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

Sent: 2/8/2021 8:39:18 AM

To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wann, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35a10ade04db43c997fbbc28531571fc-wanneg]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Thompson, Katherine (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f2c78f864ae43558adb82dc6b9a4d71-thompsonkap]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]

Subject: RE: FOR YOUR REVIEW: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Hi Renate et al.,

Looks great! Minor comments below:

- Quick view table: should we include both classes for the remdesivir + IVIG study (ITAC trial)? Defer to the experts – Antiviral/Polyclonal antibody or Antiviral/Immune Modulator?

Gilead & Other	Remdesivir and Hyperimmune Intravenous Immunoglobulin (hIVIG)	Antiviral	Intravenous	N/A	Q3 2021
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- DOD is funding both CP trials led by JHU—CSSC-001: <https://clinicaltrials.gov/ct2/show/NCT04323800> and CSSC-004: <https://clinicaltrials.gov/ct2/show/NCT04373460>. NCATS has worked closely with the PI David Sullivan, who to my understanding drafted protocols for both JHU trials and I think NIAID is a collaborator for CSSC-004 but defer to NIAID for the details. I would also mention we've (OD) worked with HHS to provide DOD with necessary testing kits and machines to accelerate their outpatient CP trials (CSSC-004) and NHLBI has collaborated with this trial on harmonizing endpoints.

- 2nd attachment: although both “like” and “associated” have both floated around, I think we previously settled on “ACTIV-Associated trials” to describe those that fall under the umbrella of ACTIV but defer to others.
 - Subhead: ACTIVE-like trials are NIH-funded, randomized, placebo-controlled clinical trials with one or more industry partners? that are at Phase 2 or later.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Sunday, February 7, 2021 3:14 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: FOR YOUR REVIEW: New Table and ACTIV-Like Addition to ACTIV Therapeutics Page

Hi all:

Attached for your review are:

- 1) Quick View Table of all therapeutics in ACTIV, including ACTIV-like trials, that will be added to the ACTIV Therapeutics page.
 - a. Note that this table does not include the new agents coming into ACTIV-2 and ACTIV-3. We will add those once they are announced. Statements are ready; NIAID is waiting on enrollment.
 - b. Also, I am waiting to hear from NIAID if CSSC-004 is NIH funded (I do not believe it is).
- 2) ACTIV-like trial information to add to the ACTIV Therapeutics page similar to other listings on the page.

I will also run these by NIAID, NHLBI, and NCATS for review.

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Sunday, February 7, 2021 8:09 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: Re: Two Items for Your Input

Thanks, David. I'll send the content around for review as soon as it's finalized.

Renate Myles
Deputy Director for Public Affairs

Office of Communications and Public Liaison
National Institutes of Health

b6

From: Wholley, David (FNIH) [T] b6
Sent: Sunday, February 7, 2021 6:54:31 AM
To: Myles, Renate (NIH/OD) [E] b6; Collins, Francis (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6; Melencio, Cheryl (FNIH) [T] b6
Cc: Burklow, John (NIH/OD) [E] b6; Fine, Amanda (NIH/OD) [E] b6; Wojtowicz, Emma (NIH/OD) [E] b6; Brodd, Lauren (NIH/OD) [E] b6; Gadbois, Ellen (NIH/OD) [E] b6; Wann, Ellen (NIH/OD) [E] b6; Meltzer, Abbey (FNIH) [T] b6; Thompson, Katherine (FNIH) [T] b6; Adam, Stacey (FNIH) [T] b6; Menetski, Joseph (FNIH) [T] b6
Subject: RE: Two Items for Your Input

Hi Renate:

Thanks for your diligence on this. These trials are on Combat COVID because they are HHS sponsored/affiliated. If we want to list only NIH trials, then they should be removed from the list. Wasn't quite clear to us when we had Deloitte put this together exactly what the criteria were to be. Thanks for your diligence on this.

From: Myles, Renate (NIH/OD) [E] b6
Sent: Friday, February 5, 2021 11:53 PM
To: Wholley, David (FNIH) [T] b6; Collins, Francis (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6; Melencio, Cheryl (FNIH) [T] b6
Cc: Burklow, John (NIH/OD) [E] b6; Fine, Amanda (NIH/OD) [E] b6; Wojtowicz, Emma (NIH/OD) [E] b6; Brodd, Lauren (NIH/OD) [E] b6; Gadbois, Ellen (NIH/OD) [E] b6; Wann, Ellen (NIH/OD) [E] b6; Meltzer, Abbey (FNIH) [T] b6; Thompson, Katherine (FNIH) [T] b6; Adam, Stacey (FNIH) [T] b6; Menetski, Joseph (FNIH) [T] b6
Subject: RE: Two Items for Your Input

Hi David:

It does not appear that NIH is funding (or is any way involved in) these three trials on the list, so I will not include them unless I hear otherwise:

- CSSC-001: <https://clinicaltrials.gov/ct2/show/NCT04323800>
- Storm Chaser: <https://clinicaltrials.gov/ct2/show/NCT04625972>
- iLeukPulm: <https://clinicaltrials.gov/ct2/show/NCT04411680>

It's unclear if NIAID is funding the one below or is just a collaborator; please let me know:

- CSSC-004: <https://clinicaltrials.gov/ct2/show/NCT04373460>

Thanks,
Renate

From: Wholley, David (FNIH) [T] b6
Sent: Friday, February 5, 2021 11:20 PM
To: Collins, Francis (NIH/OD) [E] b6; Myles, Renate (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6; Melencio, Cheryl (FNIH) [T] b6
Cc: Burklow, John (NIH/OD) [E] b6; Fine, Amanda (NIH/OD) [E] b6; Wojtowicz, Emma (NIH/OD) [E] b6; Brodd, Lauren (NIH/OD) [E] b6; Gadbois, Ellen (NIH/OD) [E] b6; Wann, Ellen (NIH/OD) [E] b6; Meltzer, Abbey (FNIH) [T] b6; Thompson, Katherine (FNIH) [T] b6; Adam, Stacey (FNIH) [T] b6

[b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Then all the trials on the list are fine.

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Friday, February 5, 2021 6:30 PM

To: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]

[b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Why does that exclude CP?

I don't think the master protocol is essential to be an ACTIV-associated trial. But it needs to be a well-powered placebo-controlled randomized trial with well defined endpoints and a DSMB.

FC

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Friday, February 5, 2021 6:24 PM

To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Adding Francis.

Francis: per our discussion, I captured ACTIV-associated trials as NIH-sponsored, randomized, placebo-controlled trial for agents in Phase 2 or higher using a master protocol. But that excludes the CP trials.

From: Wholley, David (FNIH) [T] [b6]

Sent: Friday, February 5, 2021 5:58 PM

To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Renate:

StormChaser is the prophylaxis study of AZ's nAb cocktail. They are cross-sharing sites with ACTIV-2 and using the NIH Combat COVID website—believe it is funded by OWS. So no, according to Francis's stricter definition it is not ACTIV-associated and comes off the list, as do the CP trials (which may have been referred to in the past as ACTIV-associated, I don't remember). We're having a look at what else would come off in that case, and will get back to you.

David

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Friday, February 5, 2021 5:43 PM

To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Hi David and Ashley:

John and I were discussing the table with Francis and none of us knew were familiar with the AZD7442 Storm Chaser protocol. The CT.gov record doesn't list NIH: <https://clinicaltrials.gov/ct2/show/NCT04625972>. Thanks for any additional info you can provide on it.

Also, Francis indicated to be ACTIV-associated the trial must use a master protocol for a randomized, placebo-controlled trial for agents in Phase 2 or higher. Is that how you see it as well?

Best,
Renate

From: Wholley, David (FNIH) [T] [b6]

Sent: Friday, February 5, 2021 9:39 AM

To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

That seems fine to me.

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Friday, February 5, 2021 9:16 AM

To: Wholley, David (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey

(FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Hi David and Renate,

We've previously used the definitions below to distinguish ACTIV trials from ACTIV-associated trials – feel free to edit to your preference.

ACTIV trials = NIH, other federal agencies and ~20 industry and non-profit partners

ACTIV associated trials = NIH sponsored trials with one or more industry partners

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]

Sent: Thursday, February 4, 2021 8:39 PM

To: Myles, Renate (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];

Wojtowicz, Emma (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6];

Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]

Subject: RE: Two Items for Your Input

Great. Happy to have my team review either or both.

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Thursday, February 4, 2021 8:37 PM

To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];

Wojtowicz, Emma (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6];

Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T] [b6]

Subject: Re: Two Items for Your Input

Thanks, David. We can create the ACTIV table and can coordinate with our NIH colleagues on how best to describe ACTIV-like.

Thanks,
Renate

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health

[b6]

From: Wholley, David (FNIH) [T] [b6]

Sent: Thursday, February 4, 2021 8:22:15 PM

To: Myles, Renate (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen
(NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T]
[b6]

Subject: RE: Two Items for Your Input

Renate: answers are as follows—

1. No, we have no current plans to turn the spreadsheets into a graphic table. You can do this, or we'd be happy to ask our Deloitte colleagues to do so. Please let me know. We will be happy to reach out to NIH colleagues as to how to describe the ACTIV-associated activities for the NIH ACTIV webpage, or better yet to point you to the right people at NIH to seek the information needed.
2. As for the AMP diagram, let me please circulate it to my team so we get you the exact timelines and funding numbers, at least as we see them. I see Ellens Wann and Gadbois are already copied on this note, so I will copy them on that reply so they can confirm the accuracy of our input.

Thanks, David

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Thursday, February 4, 2021 12:58 PM

To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Brodd, Lauren (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wann, Ellen
(NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Thompson, Katherine (FNIH) [T]
[b6]

Subject: Two Items for Your Input

Hi David:

I hope this note finds you well. We need your input on two items, one ACTIV related and one AMP related.

1. Francis shared the excel sheet that lists the public ACTIV and ACTIV-like therapeutics in a simple table. Is FNIH developing a graphic table that we can post to the ACTIV page? We will need to also create an ACTIV-like item for the [ACTIV Therapeutics page](#), similar to the other ACTIV therapeutic projects. We would welcome your input on how best to describe ACTIV-like projects. As you may know, we have two national stories in the works on this, a 60 Minutes piece, which Francis will be filmed for next week, and a New Yorker piece, which has been in the works for several months and is expected to publish this month (FC will have his second interview the week of Feb. 15). We'd love to be able to point both outlets to the public graph ahead of the interviews. I'm sure you also saw the [Time profile on Francis](#), which includes a lot of information about ACTIV. We're hoping he makes the cover.
2. We are in the process of preparing the rollout for the AMP AD 2.0 announcement. We discussed the [current representation of the budget on the main AMP page](#) with Ellen Gadbois and Ellen Wann and thought that an updated version of the attached graph could replace the current budget table. We would only include current projects and AMP AD 2.0. I do think there are a few things that need to be fixed in the graph, such as showing when AD 1.0 ends, which I believe overlaps with when AD 2.0 begins. We would post the graph when we announce AD 2.0, currently scheduled for Feb. 18. Let us know if you are okay with this approach.

Thanks for your input.

Best,
Renate

Renate Myles, MBA

Security Directorate Report: Affairs
of the Department of State and the Liaison
with the Intelligence Community

64 **b6**

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/10/2021 4:24:52 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: NIH COVID Therapeutics Connection

Thank you both! Sarah has looped in John B. – hopefully he will have more insight and share if this is a manufacturing issue. If so, they may be attempting to raise this with higher leadership at NIH for help.

I would defer to NIAID/FNIH on the best path forward pending the response from John.

Thanks again,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, February 10, 2021 11:14 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: NIH COVID Therapeutics Connection

Hi Ashley,

You are correct. They are currently probably about a 1/3 of the way through testing in ACTIV-5. If that data was positive, we would likely parlay that into having it join a larger Phase 3 trial in ACTIV or ACTT. This is not guaranteed, but it is the intention with any drugs that are positive in ACTIV-5.

By mired, do they mean on manufacturing? They might have been discussing that aspect with BARDA and OWS.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, February 10, 2021 11:06 AM
To: Read, Sarah (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: NIH COVID Therapeutics Connection

Hi Sarah and Stacey,

We received the congressional inquiry below regarding Lenzilumab and the request for NIH assistance to get them moving again. This request seemed strange to me given the agent is currently being tested in ACTIV-5 and I would think they are already linked with the appropriate NIH contacts.

Do you have any insight on what the issues are and if anyone at NIAID is in contact with this company? Cc'ing David for awareness.

Thanks,
Ashley

From: Robinson, Michael (NIH/OD) [E] [b6]
Sent: Wednesday, February 10, 2021 9:07 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: NIH COVID Therapeutics Connection

Ashley – Laura Berkson recommended I reach out to you regarding the below inquiry I received from Laura Friedel. I would be interested in your thoughts regarding next steps, as I don't know who in NIH should meet with this company or if a meeting is even appropriate.

Thanks for your time and help,
Mike

From: "Friedel, Laura (Appropriations)" [b6]
Date: Tuesday, February 9, 2021 at 5:31:56 PM
To: "Robinson, Michael (NIH/OD) [E]" [b6]
Subject: NIH COVID Therapeutics Connection

Hi,

I met with this company several months back. They talked to OWS and BARDA. However, are now stuck in the mud a little bit regarding a therapeutic they're developing for COVID (which is in a Phase III trial now). They seem to think that NIH might be able to help them get moving again and that Dr. Collins has been personally involved in choosing some of the OWS therapeutics (CAVEAT: I don't know if that is true).

Is there anyone at NIH they could speak to about this project? Thanks!

Laura Friedel
Clerk
Committee on Appropriations
Subcommittee on Labor, HHS, and Education
136 Dirksen Senate Office Building
Washington DC 20510

[b6]

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 9:25:47 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponeim]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Thanks, Lauren – I've sent you a separate email. We will circle back with Renate.

Thank you,
Ashley

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 5:24 PM
To: Myles, Renate (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Just wanted to let you know that I can also help cross checking the approvals if needed.

Thanks,
Lauren

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 5:21 PM
To: Parker, Ashley (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Thank you so much.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 5:18 PM
To: Myles, Renate (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Renate,

We will cross check the list of partners and let you know if we find any changes.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 4:49 PM
To: Brodd, Lauren (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Ashley:

Abbey and Greta at FNIH have been reviewing the list and sending me updates, but I would be grateful for an extra pair of eyes. I've captured new adds or deletions in tracked changes based on what they've sent me in the attached.

We also need to cross check those who gave us approval to post their names, but I think I can get Emma to do that.

Thanks so much,
Renate

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 4:33 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Happy to help if needed!

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 4:11 PM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: FW: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Renate,

Do you need help going through the list of working group members and adding those to the draft webpage or do you have Abbey or someone else helping with this?

I wanted to give Lauren a head start if this is needed.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 2:43 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6] Brodd,
Lauren (NIH/OD) [E] [b6] Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6] Schwetz, Tara (NIH/OD) [E]
[b6]
Subject: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good afternoon:

In the interest of time, I wanted to share the attached two items for both NIH and FNIH leadership review. Attached are:

1) Draft web content for a proposed NIH ACTIV web page:

- Currently, the content is based primarily on publicly available information (mostly pulled from the release).
- The only new content is the listing of the Executive Committee and Working Group members.
- Having an ACTIV webpage will provide interested stakeholders with a central resource for ACTIV information, including releases, scientific papers, blogs, etc.; will point people to the scientific portal for submitting assets; and would allow us to provide status updates, as appropriate and as desired, on ACTIV developments.
- This page can be expanded when we are ready to make more information public.

2) Draft ACTIV Communication and Legislative Strategy:

- The strategy includes proposed tactics that could be developed in the near term, as well as longer lead items that we can prepare for now as we consider appropriate timing.

If it's helpful, we'd be happy to participate in a call to talk through these recommendations with you. We look forward to your feedback.

Best,
Renate

Renate Myles, MBA

Deputy Director for Public Affairs

Office of Communications and Public Liaison

National Institutes of Health

6 [b6]

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 3:04:25 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

LOL!!!

From: George, Jill (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:01 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Recharged and in charge!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:01 AM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

I finally got some rest last night and I have some fuel this morning! 😊

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:59 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Got it. Sounds like you were one step ahead of me!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:56 AM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Rebecca,

I've noted this change to Francis and Renate – please see attached. Apologies, I did not cc the entire group but will ensure we have the right naming of the WGs.

Thanks!
Ashley

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:48 AM
To: Burklow, John (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T]

[b6] Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6] Brodd,
Lauren (NIH/OD) [E] [b6] Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6] Higgins, Lauren (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis & All,

Another picky editorial comment. On the second slide, we probably need to revise the name of the second working group to "Therapeutics Clinical Working Group." At least that was the name that FNIH asked us to use when Ashley and I were proofing your JAMA Viewpoint article yesterday evening. If that change is okay with everyone, I can have Jill George modify the slide and resend.

Rebecca

From: Burklow, John (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 10:39 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6] Wholley,
David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E]

[b6]
Cc: Fine, Amanda (NIH/OD) [E] [b6] Wojtowicz, Emma (NIH/OD) [E] [b6]
Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
Parker, Ashley (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz,
Tara (NIH/OD) [E] [b6] Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren
(NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6] Gorman, Greta (FNIH) [T]
[b6] Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi, Francis—

We have a policy, worked out with OGC, where we don't include company logos on the NIH website. That said, FNIH could certainly post them. We'll come up with a graphic that includes the partners, etc., for the NIH page.

Thanks,

John

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 10:18 AM

To: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria
(FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6] Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Wolinetz, Carrie (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6] Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6] Hallett, Adrienne
(NIH/OD) [E] [b6] Higgins, Lauren (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH)
[T] [b6] Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

How about these two?

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 8:03 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis:

You mentioned that there are images in the presentations that we can use on the webpage, but those images seem very detailed and appear to contain confidential information to me. Would you let me know which particular image that you and David feel represents the overall program but doesn't give away too much information?

We're going to start building the page in draft today (not public).

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 4:59 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Thanks, all. This is great information. I can add the items from Francis and David to the strategic comms plan and will look for comments from Abbey on the webpage/plan.

Will FNIH reach out to the EC/WG members to ask permission for listing them on the website? We'd love to get this page up this week, if possible.

Best,
Renate

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 4:38 PM
To: Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate

(NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good points.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 4:19 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate
(NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis: two other things that are possible and not already on your list below 1) the position paper from the ACTIV Vaccines WG on the issue of doing human challenge trials for Vaccines which I would hope would be ready for release by some time next week 2) a monoclonal antibodies master protocol, timing TBD (since we just received the charge this morning)

David

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 4:07 PM
To: Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence
(NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi all,

I too want to say thanks to Renate for putting together this draft of the web page – it will be great to have something posted soon.

Building off of presentations to the Leadership Team/Exec Comm, we have a number of visuals that might be appropriate to include, and that would make the web site more pleasing to the eye.

I would be in favor of including the members of the working groups (it's a very impressive list) but only after asking their permission. It would also be good to designate the co-chairs of each of the Working Groups.

The Comms and Leg plan also looks good, though obviously there are uncertainties about the timing of various newsworthy events. In the not too distant future, I think we can imagine these developments:

- 1) Publication of the JAMA Viewpoint – Howard Bauchner has been moving this along at a very rapid pace, I wouldn't be surprised to see the publication emerge within the next week. Would that be a good moment to launch the web site?
- 2) Next week's planned summit, convened by ACTIV, on development of a master protocol(s) for monoclonal Abs – the meeting itself will be closed, but it might be possible to acknowledge that it's happening – as we did for the HEAL initiative a few times.
- 3) The launch of the anticoagulation four-arm trial, with leadership from NHLBI but under the ACTIV umbrella – I don't know exactly what the time table might be
- 4) The launch of the immunomodulator trial – which awaits working out the arrangements with the companies supplying the drugs, and then doing the match with the clinical trial networks that can make this work (through ACTT3)
- 5) The development and announcement of the harmonized master protocol for vaccines, with expectation that the first volunteers will be enrolled in the Ph II/III trials around July 1.

In the midst of all this, it looks like the US government is on the brink of announcing the joint HHS-DOD Manhattan Project 2, aka Operation Warp Speed, with Moncef Slaoui (former GSK) recruited to be the big kahuna, and a general from DoD as deputy. We will need to have materials ready to explain how that all fits with ACTIV. Jon Cohen's story has already confused the issue.

FC

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 3:24 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6] Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]
[b6] Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Renate,

I have looked at the NIH ACTIV webpage outline and communications and legislative strategy. Thank you for sending them.

The webpage outline is generally fine, Abbey will send you some specific comments. Please note that we have not made the names of the WG participants public in such a visible way. I have no concerns about this, although it appears that the NIH participants are more cautious about having their names out there.

On the communications and legislative strategy, it was very good to see that Carrie's shop is featured prominently. They do an outstanding job at putting together the summaries and technical descriptions of the activities of the PPPs, as they have done in AMP and HEAL.

You have identified some portions for FNIH input. Abbey will reach out directly to you to clarify exactly what you anticipate to be the FNIH role in this.

Thanks, Maria

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 2:43 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]
Subject: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good afternoon:

In the interest of time, I wanted to share the attached two items for both NIH and FNIH leadership review. Attached are:

- 1) Draft web content for a proposed NIH ACTIV web page:
 - Currently, the content is based primarily on publicly available information (mostly pulled from the release).
 - The only new content is the listing of the Executive Committee and Working Group members.
 - Having an ACTIV webpage will provide interested stakeholders with a central resource for ACTIV information, including releases, scientific papers, blogs, etc.; will point people to the scientific portal for submitting assets; and would allow us to provide status updates, as appropriate and as desired, on ACTIV developments.
 - This page can be expanded when we are ready to make more information public.
- 2) Draft ACTIV Communication and Legislative Strategy:
 - The strategy includes proposed tactics that could be developed in the near term, as well as longer lead items that we can prepare for now as we consider appropriate timing.

If it's helpful, we'd be happy to participate in a call to talk through these recommendations with you. We look forward to your feedback.

Best,
Renate

Renate Myles MBA
Deputy Director for Public Affairs
Office of Communications and Public Affairs
National Institutes of Health
Tel: [b6]

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/13/2020 10:26:00 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Tolman, Brett [btolman@deloitte.com]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020
Attachments: activ vaccine subcommitte clinical endpoints discussion slides for distribution_final.pptx

Thanks, Mike -- I will share the updated slide you've provided and also send Dr. Collins slide 11 in the attached set.

Thanks again!
Ashley

-----Original Message-----

From: Santos, Michael (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 6:20 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tolman, Brett <btolman@deloitte.com>; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Ashley,

Well, their slides came in just in time for me to send you back this one. Of course feel free to use whatever makes sense!

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 5:59 PM
To: Santos, Michael (FNIH) [T] [b6]
Cc: Tolman, Brett <btolman@deloitte.com>; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Greatly appreciate it -- thanks, Mike!

Ashley

-----Original Message-----

From: Santos, Michael (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 5:58 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tolman, Brett <btolman@deloitte.com>; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Ashley,

Thanks for the opportunity to review. The plan has changed a bit since that slide was made, so I will made edits to it now and get it back to you within about 15 min.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 5:55 PM
To: Santos, Michael (FNIH) [T] [b6]
Cc: Tolman, Brett <btolman@deloitte.com>; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Mike,

Unfortunately, Larry has not shared the slides so I've pulled from other slides to draft something quickly to send to Dr. Collins. He is asking for the results from today's WG meeting -- can you please confirm or edit/add information where needed?

Thanks,
Ashley

-----Original Message-----

From: Santos, Michael (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 2:49 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tolman, Brett <btolman@deloitte.com>
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Ashley,

Yes, of course please feel free to reach out to Larry and Peter directly as well. If you could cc us, that would be great.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 2:48 PM
To: Santos, Michael (FNIH) [T] [b6]
Cc: Tolman, Brett <btolman@deloitte.com>
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Mike,

Thank you for the details below and I understand you are still waiting for the slides. I may need to contact Larry Corey directly to ask for the slides presented today given the time sensitive timeframe.

Thanks so much,
Ashley

-----Original Message-----

From: Santos, Michael (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 2:30 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tolman, Brett <btolman@deloitte.com>
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Ashley,

Yes, as you heard we don't have the slides yet from Larry and Peter (we asked for them in advance but they were still finishing them). Once we get them we will share them with you.

I think the report to Francis is that there will be a harmonized protocol that is expected to have agreement on primary endpoints and sampling/lab plans, among other parameters. NIAID presented a draft plan today, but deciding on those parameters will take more discussion among the group and, crucially, input from the FDA (which Marion Gruber offered a channel for).

The operational question of a shared DSMB was discussed, including suggestions for an uber-DMC that aggregates from study DMCs. The exact implementation of the concept will be worked out.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 2:09 PM
To: Santos, Michael (FNIH) [T] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Mike,

I've noted you are waiting for Larry or Peter to share the slides. Also, it seems the working group would like to further review the harmonized protocol proposal and discuss again before making final decisions about the shared DSMB ect. Is this right?

Thanks!
Ashley

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 1:40 PM
To: Santos, Michael (FNIH) [T] [b6]
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

Hi Mike,

Do we have a copy of the vaccine slides that describe the vaccine harmonized protocol being presented now? If so, can you please share so I can edit? Dr. Collins presents to the ICD group tomorrow and would like to include -- see his note below.

Is this possible?

Thanks,
Ashley

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 1:28 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Looks good, though I have done some trimming and re-arranging.

I want to add a slide to summarize what the Vaccines WG came up with today on the harmonized master protocol -- will there be a shared DSMB, shared agreement on endpoints, lab assays, etc. Can that be provided by the end of the day?

FC

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 12:43:03 AM
To: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Rebecca,

Sorry for the delay – I needed to go offline to prepare food and had been online for over 10 hours. I agree we need to be consistent with how we name the groups – I've seen both versions of how the WGs are wrtten but would go with Preclinical Therapeutics, Clinical Therapeutics, Clinical Trial Capacity, and Vaccines. The JAMA editors must have made this change.

I will go through and look for other issues as well.

Thanks,
Ashley

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 7:27 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: JAMA Viewpoint on ACTIV: please review

Hi there Dr. Parker!

Can you please take special care to make sure that all the info on the Figure is accurate? It has changed considerably from the last version that I saw and I'm uncertain whether we (NIH, FNIH) made the changes or if they were made by the JAMA graphics department. Also, have the names of the first two working groups changed to Therapeutics Preclinical and Therapeutics Clinical. We need to make sure their names are the same in the text and the figure. Thanks!
Rebecca

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 5:48 PM
To: Parker, Ashley (NIH/OD) [E] [b6] >; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: FW: JAMA Viewpoint on ACTIV: please review

Hey Ashley and Rebecca,

Can you give these galley proofs a very close read, and let me know if you find anything amiss?

Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!

Francis

From: Stacy Christiansen [b6]
Sent: Wednesday, May 13, 2020 5:22 PM
To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Howard Bauchner

b6

Karen Bucher

b6

Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,

Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

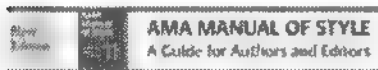
Thank you so much!

Best, Stacy

Stacy L. Christiansen, MA

Managing Editor, JAMA

Chair, AMA *Manual of Style*



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/13/2020 5:34:43 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

I think me but let's see -- I may have something we can edit. Hold tight.

-----Original Message-----

From: George, Jill (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 1:34 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Urgh. Is that you or FNIH to put that one together?

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 1:28 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Looks good, though I have done some trimming and re-arranging.

I want to add a slide to summarize what the Vaccines WG came up with today on the harmonized master protocol -- will there be a shared DSMB, shared agreement on endpoints, lab assays, etc. Can that be provided by the end of the day?

FC

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 11:23 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Francis,

Please see the attached revised set for tomorrow's ICD meeting based on your notes below and discussions at the ACTIV EC meeting this morning. There are 9 core presentation slides and I've moved the challenges/recommended actions (slides 10-11) to the end for discussion with the group.

As mentioned on our call yesterday, I think Jim would like to briefly discuss the NHP strategy/use of resources (slide 5) if time permits -- looping in Jim to confirm.

Standing by if anything else is needed.

Thanks,
Ashley

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 7:18 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
George, Jill (NIH/OD) [E] [b6]
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

Hi Francis,

Great plan -- we will adjust accordingly and standby for additional edits that may come out of the executive committee meeting.

Thanks,
Ashley

> On May 13, 2020, at 7:03 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

>

> Hi Ashley,

>

> Thanks for putting this slide set together. I'd like to see what happens in the Exec Comm/WG meeting this morning, and then we can finalize. I will want to move many of the slides to back up -- as we only have a half hour for the discussion and the presentation part shouldn't be more than 10 minutes -- the main goal is to inspire discussion. You can take out the discussion place holder slides -- I think I will try to go through the whole presentation before opening it up to questions, or we might not get to the vaccines.

>

> Francis

>

> -----Original Message-----

> From: Parker, Ashley (NIH/OD) [E] [b6]

> Sent: Tuesday, May 12, 2020 7:04 PM

> To: Collins, Francis (NIH/OD) [E] [b6]

> Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; George, Jill (NIH/OD) [E]

> [b6]

> Subject: RE: Materials: ICD Meeting Committee 5/14/2020

>

> Hi Francis,

>

> Please see attached draft ACTIV slides for the ICD meeting on Thursday. With thanks to Jill for formatting.

>

> I've included place holder slides for discussion in between the working group topics in case you want to stop and take questions/discuss -- we can delete these if you prefer to hold discussions for the end.

>

> Thank you,

> Ashley

>

> -----Original Message-----

> From: Wholley, David (FNIH) [T] [b6]

> Sent: Tuesday, May 12, 2020 7:14 AM

> To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]

> Cc: Tabak, Lawrence (NIH/OD) [E] [b6]

> Subject: RE: Materials: ICD Meeting Committee 5/14/2020

>

> Send them the Science article too

>

> -----Original Message-----

> From: Parker, Ashley (NIH/OD) [E] [b6]

> Sent: Tuesday, May 12, 2020 6:39 AM

> To: Collins, Francis (NIH/OD) [E] [b6]

> Cc: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

> Subject: Re: Materials: ICD Meeting Committee 5/14/2020

>

> Hi Francis,

>

> Happy to work with David and his team to prepare slides. Is the plan to share any updates since the ACTIV leadership meeting last Wednesday? Honestly, not sure if there's a lot to report on the working groups at the moment however I defer to David.

>

> Are there other items, anything else specifically you would like to discuss with the ICDs about ACTIV? Mention of JAMA article but this doesn't need a slide, right?

>

> Happy to help.

>

> Thanks,

> Ashley

>

>

>> On May 12, 2020, at 6:27 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

>>

>> Hi Ashley and David,

>>

>> I'll need some help preparing a presentation on ACTIV for ICs on Thursday. Larry, should there also be a RADx update? Are you hearing from ICs about this?

>>

>> FC

>>

>> From: Tabak, Lawrence (NIH/OD) [E] [b6]

>> Sent: Monday, May 11, 2020 10:22 PM
>> To: ICDDIR-L@LIST.NIH.GOV
>> Cc: IC Directors Meeting <ICDirectorsMeeting@od.nih.gov>
>> Subject: Materials: ICD Meeting Committee 5/14/2020
>>
>> Colleagues,
>>
>> We will have a IC Directors meeting Thursday, May 14, 8:30 AM to 10:00 AM by WebEx.
>>
>> Materials are attached.
>>
>> * Agenda
>> * AoU Researcher Workbench
>>
>> Materials are also posted to the ICD SharePoint site:
>> <https://sps.od.nih.gov/ICdirector/default.aspx>
>>
>> Thanks,
>> Larry
>>
>> ---
>> JOIN WEBEX MEETING
>> <https://nih.webex.com/nih/> b6
>> a Meeting number (access code): b6 Meeting password:
>> b6
>>
>>
>> * When choosing your audio connection, select either the Call Me, I will Call In*, Call Using
Computer (Desktop), or Use Internet for audio (Mobile) feature to ensure your name appears in the
participant list.
>> * *If you chose the I will Call In dial-in option, please be sure to enter your attendee ID
number that will be displayed once you are logged in from your computer in an effort to identify each
participant.
>> * Phone dial-in should only be used as a last resort means if the WebEx site, desktop or mobile app
cannot be utilized. If using a phone, when your time to speak is open, use *6 to unmute yourself. If you
use this method please email Jordan Gladman with your phone number.
>>
>> JOIN BY PHONE
>> b6 Call-in number (US/Canada)
>>
>> Access code: b6
>>
>>
>> <2020-05-14_IC Directors Agenda.docx> <IC Directors Presentation
>> 05.14.20 - long - Read-Only.pptx> <IC Directors Presentation
>> 05.14.20 - short[1] - Read-Only.pptx>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 6:22:42 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: FW: Question re: ACTIV and BayCare Health System (Florida)

Sorry – updated email thread on this topic.

From: Higgins, Joni C. [b6]
Sent: Monday, May 11, 2020 2:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6] Mauck, Danielle [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Ashley, thanks so much for making the connection.

Karen, David, it is nice to e-meet you. I am copying my colleague Danielle Mauck, who serves as BayCare's Director of Sponsored Programs and Research, to compare calendars.

We look forward to connecting with you to discuss your work and how we might help.

Joni

Joni Higgins
Federal Government Relations Manager

BayCare Health System

[b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 2:04 PM
To: Higgins, Joni C. [b6]
Cc: Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

WARNING: This email originated outside of BayCare. BE CAUTIOUS clicking links and opening attachments. Use the Report Phishing and Spam button to report malicious emails and contact the IS Service Desk with all other suspicious activity.

Hi Joni,

I am cc'ing Karen Tauntas and David Wholley with FNIH who are coordinating the efforts with ACTIV to find a time that best fits for you to speak with them.

APAR0000013351

Best,
Ashley

From: Higgins, Joni C. [b6]
Sent: Monday, May 11, 2020 1:32 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Ashley, thanks so much for your note. I appreciate the quick follow-up. Do you think a call at some point this week might be a possibility?

Joni

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 1:24 PM
To: Higgins, Joni C. [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

WARNING: This email originated outside of BayCare. BE CAUTIOUS clicking links and opening attachments. Use the Report Phishing and Spam button to report malicious emails and contact the IS Service Desk with all other suspicious activity.

Hi Joni,

Thank you for sharing BayCare Health System's interest in becoming involved as a large non-profit hospital system with ACTIV. We are in the process of developing a portal to receive submissions from interested partners however in the meantime I am triaging these request for our working groups.

I've entered the information you've provided below into our database and will share this information with leads of our ACTIV clinical capacity working group to follow up with you.

Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]



National Institutes of Health

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APAR0000013351

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/13/2020 3:52:11 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI: WF 390659 - Covid-19 Vaccine Project Concept
Attachments: 1 Covid-19 Vaccine Project Concept.msg

FYI

From: EDRMS_NO_REPLY@mail.nih.gov <EDRMS_NO_REPLY@mail.nih.gov>
Sent: Wednesday, May 13, 2020 11:44 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: WF 390659 - Selected documents from Incoming folder

Attached are the requested documents from WF 390659

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 2:02 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Covid-19 Vaccine Project Concept

Hi Ashley

This gentleman has been calling me the last couple days trying to send his concept for the ACTIV project. He asked that when you receive it you could confirm receipt. It wasn't coming through to my FNIH email so I had him send it to my personal email. I'm not sure why it doesn't go through.

Thank you

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



— Forwarded Message —

From: Howard Jeffrey Bender <[REDACTED] b6>
To: [REDACTED] b6
Sent: Monday, May 4, 2020, 01:22:55 PM EDT
Subject: Covid-19 Vaccine Project Concept

Hello, Cheryl -

Thanks for your help this morning. Here's my project concept.

Using available NIH databases, my independent research has found three one-in-a-million nucleotide links between the coronavirus and the human genome, forming the D-loop of tRNA. For the past year my work has been followed by your colleague, Kristofor Langlais <[REDACTED] b6>, who suggested I continue with lab research needed to confirm my results and speculations. My work is generally described in a YouTube for folks interested in this topic, titled Coronavirus - Using Your DNA Against You. It includes fundamental descriptions but is only about 11 minutes long.

It seems that most vaccine research is focused on finding the right immune cell proteins to keep the coronavirus from infecting human cells in the first place. I'm approaching it differently, with the speculation that at least one of those related nucleotide sequences is part of the reason Covid-19 can become so virulent. As described in the YouTube, if zapping those sequences causes Covid-19 to be a relatively mild infection, perhaps our immune system will form antibodies against it and, by extension, the deadly virus. BTW, I've found different tRNA sequences in both SARS and MERS.

I'm not looking for personal funding, but am asking for a lab researcher to test my concepts and whatever funds are necessary to do it. I suggest four levels, mentioned in the YouTube, with the project stopped for a failure at any level. Those levels are:

1. Using CRISPR or another nucleotide editing system, zap those three sequences in the virus. Whole genome nucleotide sequencing must be done to ensure those sequences have been removed.
2. Using cloned animals, infect one group with the original coronavirus and the other group with the zapped coronavirus. If the zapped animals remain much healthier than the control group, this test will be considered successful.
3. After the healthier animals have fully recovered, infect them with the original coronavirus. If they remain relatively healthy, their immune systems have developed the necessary antibodies, possibly a vaccine from the coronavirus, and this test will be considered successful.
4. Now testing can be done with human subjects, with the hope that humans will also form the necessary antibodies as a self-vaccine, with the researcher watching for any dangerous side effects and other diseases the coronavirus can still create.

If you think my ideas may have merit and can point me to an experimenter to do those tests, we may all defeat this deadly virus.

Thanks for any help you can offer.

Cheers,

Howard

Howard Jeffrey Bender, Ph.D.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 7:31:29 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: FW: Covid-19 Vaccine Project Concept

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 2:02 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Covid-19 Vaccine Project Concept

Hi Ashley

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APAR0000013364

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Cheers,

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Sent: 5/13/2020 3:41:32 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI: WF 390617 - ACTIV External Comms Strategy from FNIH
Attachments: 1 Re_ACTIV External Communications Opportunity.msg

FYI

From: EDRMS_NO_REPLY@mail.nih.gov <EDRMS_NO_REPLY@mail.nih.gov>
Sent: Wednesday, May 13, 2020 11:03 AM
To: Parker, Ashley (NIH/OD) [E] [REDACTED]
Subject: WF 390617 - Selected documents from Incoming folder

Attached are the requested documents from WF 390617

Hi Francis. Great! I'll work with the Blackrock folks.

We are in GREAT need of a communications strategy. This has been raised before. Linking it to the Leadership Group meetings makes sense. Yes, let's discuss on Monday.

As David will report on that call, the FNIH has put together an A team of expert lawyers to help us navigate legal issues that may arise. Here too we should put together a communications A team, which would include John, Abbey, selected partners' Comms folks and perhaps call in some support from agency experts.

We need to figure out the key audiences and then craft strategies for each. There is a need for internal and external strategies. Internal to NIH, to make sure all ICs are up to speed and to partner company staff and leadership so that the right and left hands are in sync. The external strategy would be broader, of course - academics to get them excited and eager to be involved, the Hill to garner their support, etc.

One potential outreach, among more traditional ones, is to create a social media tool kit, with key, pre-drafted messages for Twitter, Facebook and LinkedIn that gets amplified by all partners. Another may be to get some video "interviews", like Blackrock and Keystone Symposium (they have asked what they can do to help). However, because of time demands, we will need to be very disciplined and strategic.

Let me noodle on this, M.

From: "Collins, Francis (NIH/OD) [E]" [REDACTED]
Date: Saturday, May 2, 2020 at 7:48:06 PM
To: "Freire, Maria (FNIH) [T]" [REDACTED]
Cc: "Burklow, John (NIH/OD) [E]" [REDACTED] "Tabak, Lawrence (NIH/OD) [E]" [REDACTED], "Wholley, David (FNIH) [T]" [REDACTED] "Parker, Ashley (NIH/OD) [E]" [REDACTED]
Subject: RE: ACTIV External Communications Opportunity

Hi Maria,

I don't know BAI and I'll have to trust the information from you and John about its reach, but if you think it's worth it, I'd be up for this kind of a fireside chat.

On a highly related note, we had a very significant Zoom meeting this afternoon with the ACTIV vaccines co-chairs – Doug Lowy and Kathrin Jensen. Tony Fauci, John Mascola, and Cliff Lane joined the call to outline the potential of a master protocol that could compare multiple vaccine programs in a rapidly enrolling Phase II/III trial, and could start as soon as July 1. Yes, I said July 1.

Doug Lowy noted at the end of the call that there are a great many things going on with ACTIV that are not widely known by the public or the scientific community – it's time to implement a communications strategy. One part of that might be the ACTIV article for JAMA that Paul Stoffels and I are co-authoring (he has agreed). I am working on that this weekend, starting from Ashley's draft. But another mechanism for ongoing public disclosure would be to put out some kind of communication every two weeks, timed to follow the Leadership meetings. David and I thought that made a lot of sense. Such a communication would need to involve the capable comms shops at NIH and FNIH, but also the comms shops of the other partners (including industry). Maybe we can talk about this on Monday at our War Room meeting?

FC

From: Freire, Maria (FNIH) [T] [b6]

Sent: Saturday, May 2, 2020 3:39 PM

To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E]

Subject: ACTIV External Communications Opportunity

Francis,

Russ Steenberg, is a member of our Board and Managing Director and Global Head of BlackRock Private Equity Partners (PEP), within BlackRock Alternative Investors (BAI). BAI has a forum that is broadcast to clients, investors and Blackrock staff all over the world.

A few weeks ago, when ACTIV was launched, Russ approached me to see if you would be willing to do a "fireside" chat (live or taped) to be broadcast as part of their coronavirus education to large audiences. My sense is that the time is right for you to do something like this – in mid-may – to get visibility for ACTIV and to firmly plant the ACTIV "flag" with a broader audience. There is a lot of noise and press out there for other initiatives, so this may be a good communications tool for you.

I reached out to John, copied here, last night to get his sense and he is supportive. BAI would produce and support this piece. Please let me know if this is of any interest.

Best, M.

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 5/3/2020 1:39:31 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
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Date: Saturday, May 2, 2020 at 7:48:06 PM
To: "Freire, Maria (FNIH) [T]" [b6]
Cc: "Burklow, John (NIH/OD)" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Parker, Ashley (NIH/OD)" [b6]
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Sent: 5/14/2020 3:19:02 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Thanks. I shared my edits with Rebecca and we've discussed— Rebecca will send our collective comments tonight.

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 7:20 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Yes, but early please.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 7:14 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Francis,

I will take a close look at this – can I send anything I find tomorrow?

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 5:48 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: FW: JAMA Viewpoint on ACTIV: please review

Hey Ashley and Rebecca,

Can you give these galley proofs a very close read, and let me know if you find anything amiss?

Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!

Francis

From: Stacy Christiansen [b6]
Sent: Wednesday, May 13, 2020 5:22 PM
To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Howard Bauchner [b6] >; Karen Bucher [b6]
Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,
Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

Thank you so much!

Best, Stacy

Stacy L. Christiansen, MA
Managing Editor, JAMA
Chair, AMA Manual of Style



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Sent: 5/14/2020 3:10:34 AM
To: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]
Subject: RE: JAMA Viewpoint on ACTIV: please review-KolbergProof
Attachments: JVP200113(1)_editsAP 1109PM.pdf

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 10:51 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review-KolbergProof

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 10:24 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: JAMA Viewpoint on ACTIV: please review-KolbergProof

Please call me at [b6]

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Wednesday, May 13, 2020 at 10:13:02 PM
To: "Kolberg, Rebecca (NIH/OD) [E]" [b6]
Cc: "Wholley, David (FNIH) [T]" [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review-KolbergProof

Hi Rebecca,

I am going through the article now and highlighting items I find in the PDF. Should I send them your way once I am done? Shouldn't take me much longer.

Thanks,
Ashley

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 10:08 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review-KolbergProof

Hi Ashley (& David, if you have interest),
Following my review of the JAMA proofs, below are my routine fixes and some important issues (mainly re figure) that I've flagged for FC's input. I can go ahead and send them directly to him tonight (with cc to all on the chain) for his review in the morning. If you have anything you'd like to add, send them my way and I can incorporate. Or if you'd prefer to weave my comments into yours and send these to him later tonight, that's cool too. Just let me know how you'd like to proceed!

Rebecca

Text

Page 1, Column 2, Paragraph 2, Final Sentence: Fix agency name: Department of Veterans Affairs (VA)

Note: It's no longer the Veteran's Administration, <https://www.va.gov/>

Page 2, Column 1, Paragraph 2, Sentence 1. Add space between "The" and "Preclinical"

Page 2, Column 1, Paragraph 3, Sentence 1. Change the name to: **The Therapeutics Clinical Working Group**

Page 2, Column 1&2, Final Sentence. **Note to FC:** Suggest cutting due to redundancy. It makes the same point as the preceding sentence, only in more general terms. Recommended cut is highlighted: "Of the 39 agents that underwent final prioritization review, the group identified 6 agents—including immunomodulators and supportive therapies--that it proposes to move forward into the master protocol clinical trial(s) expected to begin later in May. This working group has also developed a master protocol for clinical trials of prioritized therapeutic candidates."

Figure

Note: I'm unaware of any follow-up communications between the authors and JAMA graphics staff related to the Figure that was submitted. If there were, some of my comments may not be relevant.

Top box. Submitted figure had the Partnership Leadership Group as a separate box to the left, connected by a dotted line to another box listing Executive Committee members. **Q for FC:** Does this nested box depiction work for you? Or should we ask JAMA to go back to the arrangement in your original figure?

Placement of "ACTIV database and inventory." Submitted figure had this text placed at the bottom in a banner with arrows indicating activities across working groups. This text now appears inside a static box in the middle, making it look (at least to this viewer) like it is a higher-level activity than those of the working groups. **Q to FC:** Does this change work for you? Or should we ask JAMA to go back to the arrangement in your original figure?

Working Group Names. Change "Therapeutics preclinical" to "Preclinical"

References

Qs to FC/Renate: Will the website being cited in Reference 5 actually be a portal or have language indicating that the portal will soon reside here? If not, cut "Portal" from Reference. Do we have a placeholder URL that we can provide to JAMA editors?

Acknowledgements

Change agency name from "the Veterans Administration" to "VA"

Note: It's Department of Veterans Affairs (VA), <https://www.va.gov/>

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Wednesday, May 13, 2020 5:48 PM

To: Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]

Cc: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]

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Francis

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Sent: Wednesday, May 13, 2020 5:22 PM

To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>

Cc: Howard Bauchner; [REDACTED] b6 [REDACTED]; Karen Bucher [REDACTED] b6 [REDACTED]

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Stacy L. Christiansen, MA

Managing Editor, *JAMA*

Chair, *AMA Manual of Style*



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Sent: 5/13/2020 12:36:08 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Subject: Re: Follow-up Materials from May 6 ACTIV Leadership Teleconference

Thanks, David!

Ashley

On May 12, 2020, at 8:13 PM, Wholley, David (FNIH) [T] [b6] wrote:

Ashley, fyi per an earlier point we discussed last night. Company listing is Roche/Genentech

From: Pao, William [b6]
Sent: Sunday, May 10, 2020 11:19 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: Follow-up Materials from May 6 ACTIV Leadership Teleconference

Hi David,

The minutes look good.

I had a very minor point – technically, I am the Head of Pharma Research and Early Development for Roche (Roche pRED), not Genentech (Mike Varney is the head of Genentech Research and Early Development). But I am representing the entire Roche Group for ACTIV.

Best,

William

From: Melencio, Cheryl (FNIH) [T] [b6] **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Saturday, May 9, 2020 12:55 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: Follow-up Materials from May 6 ACTIV Leadership Teleconference

Dear Leadership Team:

Please find attached the meeting notes from our Leadership Team meeting this past Wednesday, May 6. Any questions and comments from the chatbox sessions that are not fully addressed in the body of the notes may be found in a brief "Q&A" appendix at the end of the document.

As always, comments and questions are welcome and may be sent to me. Thank you again to all the time and effort put into this by our Working Group Co-chairs and for their terrific presentations. And thanks to all of you for your insights and comments, and for making this such a productive discussion.

Regards,

David Wholley

APAR0000013393

Senior Vice President, Research Partnerships
Foundation for the National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/12/2020 10:17:56 PM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: Fwd: CNN inquiry

FYI

Begin forwarded message:

From: "Myles, Renate (NIH/OD) [E]" [b6]
Date: May 12, 2020 at 6:11:58 PM EDT
To: "Collins, Francis (NIH/OD) [E]" [b6] "Tabak, Lawrence (NIH/OD) [E]" [b6] "Wolinetz, Carrie (NIH/OD) [E]" [b6] "Parker, Ashley (NIH/OD) [E]" [b6], "Hallett, Adrienne (NIH/OD) [E]" [b6]
Cc: "Burklow, John (NIH/OD) [E]" [b6]
Subject: FW: CNN inquiry

Just an FYI, there seems to be a major leak from inside the working groups. This is the second reporter who seems to have very specific info on the inner workings of the working group.

From: Cohen, Elizabeth [b6]
Sent: Tuesday, May 12, 2020 4:20 PM
To: Gorman, Greta (FNIH) [T] [b6]
Cc: Meltzer, Abbey (FNIH) [T] [b6]
Subject: Re: hello from CNN - question on deadline

Hi Greta,

Thanks for your email.

I understand that ACTIV is considering one efficacy trial in the summer for several candidates that are ready, and that they will share a control (placebo) group. I'm writing this up this evening and would love to include comment from someone at FNIH. Could you please respond in the next few hours? Thanks.
Elizabeth

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/12/2020 12:56:49 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Viewpoint on ACTIV

Ok, I think you have what you need – 18 companies listed below in alphabetical order.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 8:51 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Viewpoint on ACTIV

No attachment, just the text below..

Sent from my iPhone

On May 12, 2020, at 8:25 AM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

Can you forward me the attachment – I didn't have that, pasting the companies below.

- AbbVie
- Amgen
- AstraZeneca
- Bristol Myers Squibb
- Eisai
- Eli Lilly and Company
- Evotec
- Gilead
- GlaxoSmithKline
- Johnson & Johnson
- KSQ Therapeutics
- Merck & Co., Inc.
- Novartis
- Pfizer
- Roche
- Sanofi
- Takeda
- Vir Biotechnology

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 8:13 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Fwd: Viewpoint on ACTIV

Can you insert company names (;alphabetically) and send back to me?

Sent from my iPhone

Begin forwarded message:

From: Howard Bauchner <[REDACTED] b6 [REDACTED]>
Date: May 12, 2020 at 7:17:08 AM EDT
To: "Collins, Francis (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>
Cc: Phil Fontanarosa <[REDACTED] b6 [REDACTED]>
Subject: RE: Viewpoint on ACTIV

Minor edits – can you name the companies – folks will want to know who they are. And would delete the word courage.

HCB

We would like to acknowledge Ashley Parker, Rebecca Kolberg, and David Wholley for their help in preparation of this manuscript. We would also like to thank the leadership of more than a dozen biopharmaceutical companies, INCLUDING CAN YOU NAME THE COMPANIES, several NIH Institutes (especially NIAID), the FDA, BARDA, CDC, the European Medicines Agency, the Department of Defense, the Veterans Administration, and the Foundation for NIH for their (PLEASE DELETE courage) commitment in engaging in this unprecedented partnership."

Francis

From: Howard Bauchner <[REDACTED] b6 [REDACTED]>
Sent: Monday, May 11, 2020 3:21 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Cc: Phil Fontanarosa <[REDACTED] b6 [REDACTED]>; Stoffels, Paul <[REDACTED] b6 [REDACTED]>; Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Subject: RE: Viewpoint on ACTIV

Should not be a problem – just send along the names and I will take care of it.

We would like to acknowledged the following individuals who are ...: xx, xx, xx,

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

[Listen to my chats with authors](#)

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 2:19 PM
To: Howard Bauchner [b6]
Cc: Phil Fontanarosa [b6]; Stoffels, Paul [b6]
[b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Viewpoint on ACTIV

[Warning External Email]

Good point! Can we get you an Acknowledgement to squeeze in?

Francis

From: Howard Bauchner [b6]
Sent: Monday, May 11, 2020 10:24 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Phil Fontanarosa [b6]; Stoffels, Paul [b6]
[b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Viewpoint on ACTIV

Francis/Paul

Thinking it would be helpful to name the folks from industry you have collaborated with at the end of the article – in additional information – suspect most readers will want to know who.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my [chats with authors](#)

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 9:03 AM
To: Howard Bauchner [b6]
Cc: Phil Fontanarosa [b6]; Stoffels, Paul [b6]
[b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Viewpoint on ACTIV

[Warning External Email]

Here you go. Many thanks for your very rapid response!!

Best, Francis

From: Howard Bauchner [b6]
Sent: Sunday, May 10, 2020 1:47 PM
To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Phil Fontanarosa [b6]

Subject: Re: Viewpoint on ACTIV

Francis – attached are our edits –

Just return a clean copy and one with track changes to Phil and me.

Stay healthy.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my [chats with authors](#)

From: Francis Collins [b6]
Date: Sunday, May 10, 2020 at 11:32 AM
To: Howard Bauchner [b6]
Cc: "Stoffels, Paul" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], Tony Fauci [b6], "Burklow, John (NIH/OD) [E]" [b6], "Myles, Renate (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Kolberg, Rebecca (NIH/OD) [E]" [b6], "Wolinetz, Carrie (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Freire, Maria (FNIH) [T]" [b6]
Subject: Viewpoint on ACTIV

[Warning External Email]

Dear Howard,

On behalf of Paul Stoffels and myself, please see attached a Viewpoint on the ACTIV public-private partnership that we would like to have considered for publication in JAMA. Because of the rapidly moving events surrounding the COVID-19 pandemic, your offer to review this quickly is much appreciated.

I will serve as corresponding author.

Many thanks, Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/12/2020 4:00:38 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: Pre-call for ACTIV Leadership Call #4
Location: see webex below
Start: 6/1/2020 4:15:00 PM
End: 6/1/2020 5:15:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/12/2020 3:14:44 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV Executive Committee Teleconference

Location: <https://fnih.zoom.us/j/9181212555> b6

Start: 5/20/2020 7:30:00 PM

End: 5/20/2020 9:00:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/12/2020 3:03:29 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: Accepted: ACTIV Response Partnership Leadership Team Meeting #4

Location: <https://fnih.zoom.us/j/91812121212> **b6**

Start: 6/3/2020 4:00:00 PM

End: 6/3/2020 5:30:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/9/2021 1:54:26 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: Accepted: ACTIV Vaccines Working Group meeting
Location: [https://fnih.zoom.us/j/](https://fnih.zoom.us/j/66666666666666666666666666666666)b6
Start: 2/11/2021 4:30:00 PM
End: 2/11/2021 5:45:00 PM
Show Time As: Busy